AN OUTCOME-ORIENTED EVALUATION OF PRE-HOSPITAL EMERGENCY CORONARY CARE

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AN OUTCOME-ORIENTED EVALUATION OF PRE-HOSPITAL EMERGENCY CORONARY CARE

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SUMMARY

In the past, emergency medical services (EMS) have been evaluated primarily in terms of input (e.g., number of ambulances) or process (e.g., ambulance response time) measures. Although these measures have value in the operational management of EMS systems, they do not directly assess the effect of the EMS system on the patient.

It is generally recognized that evaluation in terms of patient outcome is the ultimate measure of system effectiveness. Unfortunately, patient outcome research has been somewhat limited, especially in relation to EMS. Moreover, the majority of outcome research has been focused upon final patient outcome, which represents the additive effects of all medical resources, including EMS, that have been applied to patient care. A more appropriate outcome-oriented evaluation of EMS needs to consider some measure other than final outcome in order to isolate those effects that are directly attributable to EMS intervention.

This thesis presents the development and validation of an EMS evaluation model that is based on the concept of intermediate patient outcome. Specifically, two evaluative measures were developed, an index of initial condition (IIC) and a stabilization outcome measure (SOM). The IIC is a measure of the severity of patient condition and the SOM is

an indicator of the extent to which a patient's condition is "stabilized" as a result of emergency medical treatment. Both measures were developed for the specific case of acute myocardial infarction.

A multiple linear regression model was used to develop the IIC as a function of vital signs (as measured upon arrival of the ambulance on the scene of the emergency), age, sex, heart size, and past cardiac history. This model was found to be a reasonably valid predictor of hospital mortality, providing correct classifications in 88 per cent of the cases.

The SOM was also developed through use of multiple linear regression. This model expresses physician perception of level of stabilization as a function of age, sex, and both pre- and post-intervention measurements of vital signs. Two independent panels of physicians were utilized to provide subjective estimates of stabilization. Both intra-panel and inter-panel agreement were demonstrated. The resulting regression model was highly significant, having a coefficient of correlation of +.93.

In addition, the relationship between stabilization and final outcome (in terms of hospital mortality) was examined. It was shown that the "stable" patient has a greater chance of surviving than does the "unstable" patient.

CHAPTER I

INTRODUCTION

This thesis presents the development and validation of a model to evaluate pre-hospital emergency coronary care (PHECC) that is based upon the concept of intermediate patient outcome. By way of introduction, the motivation for evaluating PHECC and the rationale for basing evaluation on patient outcome are discussed.

Pre-Hospital Emergency Coronary Care

Each year, approximately one million persons in the United States experience a heart attack or an acute myocardial infarction (AMI).[1] Of these, it has been estimated that 55 to 70 per cent die as a result of the infarction (American

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[1]The medical terminology used throughout the PHECC literature is by no means consistently applied. Thus, a brief explanation of the various terms used is in order: Coronary disease, or coronary artery disease, describes a degenerative disease of the arteries that supply the heart in which the arterial wall is progressively narrowed or occluded. Other terms used to describe this phenomenon include coronary heart disease and ischemic heart disease. The principal manifestation of coronary artery disease, the "heart attack," represents damage to a portion of the heart muscle, the myocardium, since a portion of the heart is deprived of oxygen due to arterial occlusion. The correct term for this manifestation is myocardial infarction, although coronary thrombosis and coronary occlusion are also used. Throughout the remainder of the thesis, the term myocardial infarction or acute myocardial infarction will be used. (Selzer, 1966, pp. 149-162)

Heart Association Committee on Cardio-Pulmonary Resuscitation and Emergency Coronary Care, 1974, p. 838). The mortality from ischemic heart disease is twice that of cancer and over seven times that of trauma (Critical Care Seminar Prospectus, 1975, p. I-1). In fact, the American Heart Association Committee on Cardio-Pulmonary Resuscitation and Emergency Coronary Care states that sudden death from heart attack is the "most important medical emergency today" (1974, p. 838).

In recent years, the introduction of coronary care units (CCUs) have drastically reduced the in-hospital mortality rate from AMIs through intensive monitoring and aggressive management of cardiac patients (Langhorne, 1967, p. 92; Huszar, 1974, p. i). As Rose and Press (1972, p. 63) point out, "once a patient with acute myocardial infarction reaches a hospital with a well-equipped and well operated coronary care unit, his chances of surviving are excellent."

Furthermore, Norris and Caunt (1973, p. 342) observe that AMI patients surviving long enough to reach CCUs have a mortality rate of 15 to 20 percent, a rate appreciably lower than that of overall AMI mortality. Although CCUs have reduced mortality, it is unlikely that further substantial improvements can be achieved (Pantridge and Adgey, 1969, p. 666). As Sidel (1969, p. 674) reasons, "the residual 20 per cent of heart attack patients who die in-hospital deaths die largely from intractable heart failure and cardiogenic shock. The extent of damage to the myocardium probably

precludes substantial salvage whatever the vigor of current support measures." This sentiment is echoed by many other investigators who note the mortality rate of shock associated with AMI has improved very little despite the availability of CCUs (Weil and Shubin, 1973, p. 32).

Perhaps most important is the fact that most deaths due to AMI occur before the victim reaches the hospital (Pantridge and Adgey, 1969, p. 666; Simon and Alonzo, 1973, p. 163). Different sources cite pre-hospital mortality rates ranging from 33 per cent to 70 per cent (Sidel, 1969, p. 674; Richupan and Anderson, 1975, p. 65). Furthermore, some 40 to 75 per cent of all AMI-related deaths occur within one hour of the initial conset of symptoms (Fulton, Julian, and Oliver, 1969, p. 182; Pantridge, 1969, p. 666; Adgey et al., 1969, p. 7607; Carter, 1974, p. 287). In spite of the alarmingly high percentage of sudden deaths, one source estimates that some 75 per cent of these deaths might be prevented, given prompt emergency treatment (Business Week, 1969, p. 96).

In recognition of the immense life-saving potential of immediate and effective PHECC, Pantridge and Geddes (1967) transposed the concepts of CCUs to pre-hospital intervention in the form of mobile coronary care units (MCCUs). Pantridge's pioneering efforts with MCCUs sparked renewed interest and efforts in the delivery of PHECC, and as a result, many federal, state, and local groups have initiated massive

programs aimed at reducing death due to AMI. Such programs include, but are not limited to, new and more sophisticated equipment, improved communications and emergency medical access, increased training for ambulance personnel, new treatment protocols, mass training of lay persons in basic first aid measures (specifically cardio-pulmonary resuscitation) and identification and education of high-risk patients. If AMI mortality is to be substantially reduced in a reasonably cost-effective manner, community resources must be optimally allocated to the most effective modes of intervention. As summarized by participants in the Bethesda Conference on Early Care for the Acute Coronary Suspect (American College of Cardiology, 1969, pp. 607-608),

> Since there are limited resources available for community programs and many needs are to be met, it is important to build a system of evaluation into these programs which will determine their effectiveness and usefulness on a continuing basis.

Development of a conceptual basis for such a system of evaluation is the central purpose of this thesis. The rationale for the approach taken in its development is elaborated below.

Outcome Evaluation

Given the motivation for evaluating programs of PHECC, an appropriate evaluative philosophy must be selected. Moreover, selection of an evaluative approach is not a problem solely limited to the area of PHECC, but rather, is

a central issue in emergency medical services (EMS) evaluation as a whole.

Donnebedian (1966) has classified evaluation of health services into three categories--structure, process and outcome. Structural, or input measures in EMS generally include vehicle counts, service incidents, ambulance equipment, level of personnel training, descriptions of the population and area served and specification of operating procedures (Willemain, 1975, p. 144). Process measures deal with the dynamic aspects of system efficiency such as ambulance response times and associated delay times, and the frequency and type of aid administered by ambulance personnel (Willemain, 1975, pp. 145-146). Finally, outcome measures address patient condition and range from aggregate mortality rates to complex measures of disability based on functional status six and twelve months after the acute emergency episode (Willemain, 1975, pp. 146-147).

In the past, EMS have been evaluated primarily in terms of structure and process measures (Gibson, 1973, p. 428). Although these types of measures have value in the operational management of EMS systems, they do not directly assess the effects of EMS intervention on the patient. As Gibson (1974, p. 18) states, "while evaluation of process is a decided, though belated improvement over description of structure, it is no substitute for evaluation of outcome." Starfield (1974, p. 39) reinforces this viewpoint in

describing outcome as "the ultimate test of the efficacy and effectiveness of medical care."

As noted above, it is generally recognized that evaluation in terms of patient outcome is the ultimate measure of system effectiveness. Unfortunately, patient outcome research has been somewhat limited, especially in relation to EMS. Moreover, the majority of outcome research has been focused upon final patient outcome, which represents the additive effects of all medical resources, including EMS, applied to patient care. A more appropriate outcome-oriented evaluation of EMS must consider some measure other than final outcome in order to isolate effects directly attributable to EMS intervention.

Measurement of outcome at points closer to the time of EMS intervention would seem to be more pertinent for EMS evaluation. In a recent study, Richupan and Anderson (1976, p. 67) suggest that outcome be measured prior to admission to the emergency department and prior to hospital admission in addition to measurement at points on and after discharge. Consideration of these intermediate patient outcomes can gain further relevance to EMS intervention if expressed in terms compatible with the process and functions of emergency medical care. Along this line of thought, Myrick (1974) defines the function of the EMS system in terms of providing stabilizing care to persons with life-threatening or potentially disabling conditions. Hence, the approach to the

measurement of outcome taken in this thesis is to develop "stabilization outcome" measures which describe the degree to which a patient's condition is stabilized, after the point of EMS intervention.

Objectives of the Thesis

Based upon the motivation and rationale for evaluating PHECC in terms of stabilization outcome, the following objectives were formulated as meaningful and appropriate research goals for this thesis:

1. To develop a classification scheme for categorizing the initial condition of acute myocardial infarction patients.

2. To develop and test a stabilization outcome model representing a patient's condition after interaction with the EMS system, specifically examining the case of acute myocardial infarction.

In the pursuit of the above objectives, an index of initial condition and a stabilization outcome measure were developed. As a prelude to that development, the following chapters describe the previous research completed in this area and the scope and limitations of the research effort.

CHAPTER II

REVIEW OF THE LITERATURE

The following chapter presents a brief review of past research in the areas of EMS severity indices and outcome measures, as each relates to the present research. Specifically, the need for this type of research is addressed, followed by a review of past research and an assessment of the implications for the present research.

The Need for Outcome/Severity Research

Patient outcome is a subject that has received much attention in the literature; however, very little definitive research has been conducted. As stated by Gibson (1974, p. 107), "Ironically, the most important aspect of emergency medical services--outcome of the patient's condition--has been studied least." Donnebedian (1970, p. 131) reinforces the importance of measuring outcomes as he cites outcomes as "the most concrete indicators of failure or success in care."

McClure (1973, p. 334-5) views the lack of the use of patient outcome measures of quality as a failure to manage by objectives. He states that a system which fails to manage by objectives tends to maximize on secondary objectives. For example, consider response time. Many EMS systems use response time as a primary design and evaluation criterion.

However, this measure only gives an indirect indication of system performance; it is not explicitly linked with outcome. In fact, it has been suggested that patients in the EMS system die or survive "solely as a function of their condition and that the only effect of EMS expenditures is influencing when and where death takes place" (Gibson, 1974, p. 108). Thus, it seems clear, if not mandatory, that outcome in conjunction with EMS intervention strategies must be examined in order to prove or disprove this hypothesis.

Gibson (1974, p. 109) further suggests that in order to "secure valid measures, a sufficiently large series for each clinical condition and each EMS element will be necessary so that the effect of clinical severity can be factored out... and the independent effect of each EMS element on outcome may be evaluated." However, in the absence of such large series, as is the case in almost any practical research setting, a reliable indicator of severity (e.g., an index of initial condition) is necessary.

Past Efforts in EMS Outcome Research

Representative of the approaches to EMS evaluation which have not considered outcome is a study conducted by the Computer Sciences Corporation (1973) for the U. S. Department of Transportation.

Computer Sciences Corporation (1973)

In this research, it was concluded that a mathematical

evaluation of an EMS system based on explicit measurement of factors such as survival rates, extent of recuperation, et cetera, directly related to the quality of an EMS system was "difficult if not impossible," to attain (1973, p. 4-3). Therefore, evaluation was based on quantative measurement of indirect parameters of system effectiveness and quality. These "proxy" factors included extent of emergency care and equipment, system audit and monitoring, and system cost (1973, p. 4-4).

Investigators Citing Death as an Outcome

Much of the research in patient outcome has concentrated on death, or alternately survival, as an outcome. However, as Gibson (1974, p. 109) observes, aggregate death rates are poor EMS evaluation measures because EMS has little effect on them. A slight refinement in the concept of the simple dichotomy of living versus dead is the notion of "salvageable" or "preventable" deaths. As Gibson further states, "EMS outcome measures currently are mainly clinical impressions from autopsy and other records that a given number of deaths were 'salvageable'." In this regard, Rhodes (1975, p. 180) claims that the "concept of salvageable or irreversible deaths may be the most practical and useful approach to measuring patient outcome by survival/mortality." This concept is exemplified by the works of Frey et al., Gertner et al., and Rhodes.

Frey et al. (1969) Frey et al. investigated the

autopsy protocols of 159 patients dying in traffic accidents in order to determine how many of the victims might have survived if skilled resuscitation had been available in pre-hospital care. It was assumed that those performing resuscitation would have the skills and equipment necessary to effectively administer intravenous fluid therapy and endotracheal intubation (1969, p. 293). Implicit in the condition of available resuscitative care were assumptions concerning the nature of the injury, timing of the resuscitative effort, and definitive hospital treatment (1969, pp. 298-99). This study classified 28 individuals as salvageable. Hence, outcomes were defined in terms of the percentage of individuals that were probably salvageable given specific intervention strategies (1969, p. 301).

Gertner et al. (1972). Gertner et al. later applied the "salvageable" concept to injury management in the hospital. In this study, hospital records and post-mortem examinations of 33 traffic fatalities due to intra-abdominal injuries were reviewed (1972, p. 426). All patients, with the exception of one, were alive when reaching the hospital; therefore, attention was directed toward emergency measures administered in the hospital. Analyses indicated that half the patients could have been salvaged, given prompt and proper diagnosis and treatment (1972, p. 431).

Rhodes (1975). Rhodes, as part of the Jacksonville experimental Health Delivery System demonstration project

extended the concept of salvageable/not salvageable to include a six point classification of outcome, as follows.

1. Alive-resuscitated
2. Alive-death prevented by medical intervention
3. Alive-no danger of death
4. Dead-could have been resuscitated
5. Dead-preventable by medical intervention
6. Dead-beyond assistance-irreversible

Accordingly, categories four and five can be considered as salvageable.

Survival as Related to Stabilization as an Outcome

The research of Myrick (1974) assumed that patient outcome is dependent upon the stabilization procedures available to a patient and the associated time that the procedures are administered. Three injury categories (airway emergencies, flail chest, and ruptured spleen) were chosen for study, with survival as the appropriate outcome measure.

For each of these injury categories, the effect on patient survival due to specific intervention strategies (stabilization procedures) administered at different times was determined. This was accomplished by using a group consensus procedure known as the Delphi technique. Using this procedure, a group of physicians for each injury category was asked to estimate the number of patients expected to survive given certain time-treatment combinations. Results of this endeavor compared very favorably with specific care data from the Illinois Trauma Registry (1974, pp. vii-viii).

In addition, Myrick commented on the need for

consideration of multiple injuries and measures of disability versus survival measures. It was suggested that these factors be considered in a similar stabilization methodology (1974, pp. 174-76).

Indicators of Disability/Disfunction as an Outcome

Bush, Blischke, and Berry (1973) have conducted the most significant research with disability/disfunction outcome scales for EMS evaluation. This work is based on a number of years of research with health status indices as conducted by Bush, Chen, and Zaremba (1971); Bush, Chen, and Patrick (1972); and Patrick, Bush, and Chen (1973); among others.

Bush, Blischke, and Berry (1973). This research proposes the following general outcome model (1973, p. 3):

$$W_j = f(x_1, x_2, \ldots, x_k)$$

where:

j = index for the function level observed as the outcome for a given patient on follow-up.

W_j = level-of-well-being assigned to function level j.

$(x_1, x_2, \ldots, x_k)$ = values of the explanatory (patient condition, structure, and process) variables observed for each case.

f = a functional relationship between the dependent variable, W_j, and the independent variables, x_i.

The dependent variable, Level-of-Well-Being, is a composite

outcome measure consisting of three scales. These scales are (1) mobility, (2) physical activity, and (3) social activity. Combinations of different levels of these scales yield "at least thirty levels for classifying dysfunction from complete well-being to death. A unit from 0.0 for death to 1.0 for optimum function maps the levels onto a single, point in time, scale of well-being" (1973, p. 6).

Bush et al. note that the above outcome measure also has a second dimension, prognosis.[2] Prognosis was defined as an individual's probability of transition to other functional levels over time (1973, p. 6).

Gibson (1974)

Finally, in a review of EMS research and evaluation, Gibson suggests the following set of outcome measures:

1. Percent of patients who survive.
2. Disability days per patient, defined as days from onset of precipitating condition to complete resumption of patient's normal role and comprising (a) days confined to bed, (b) days confined to home although not to bed, and (c) days patient could not fully engage in normal activities because of clinical condition.
3. Percent of cases in which patients are residually impaired in activities of daily living.
4. Age- and sex-specific death rates from EMS-related causes of death.
5. Percent of EMS-related deaths of persons entering system before death.

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[2]This part of the index was not yet developed.

6. Percent of patients satisfied with EMS.

7. Patient score on the Cornell Medical Index (symptom score) 6 months and 12 months after EMS incident.

8. Percent of cases in which patient died at scene on arrival of ambulance, at scene after arrival of ambulance, en route to hospital, and after hospital arrival.

9. Mean number of minutes from onset to death (1974, p. 109).

Past Efforts in the Development of EMS Severity Indices

The following sections are representative of recent research in the development of EMS severity indices. All of the measures to be discussed are severity of injury as opposed to severity of illness indices. Although the index of initial condition developed herein is an index of severity of illness, it is felt that many of the concepts used in the construction of the injury measures are applicable to the present research.

Williams and Schamadan (1969)

An empirically-constructed index of severity, SIMBOL, was developed by Williams and Schamadan for the purpose of providing uniform initial evaluations of accident victims. The SIMBOL rating is composed of two numbers--one representing the patient status (the status score) and another representing a patient's potential for recovery (the predictor score). The status score is based on measurement of vital signs whereas the predictor score is based on the status score,

age, weight, and extent of trauma. The index as presented was not validated.

Committee on Medical Aspects of Automotive Safety (1971)

The Committee on Medical Aspects of Automotive Safety developed the Abbreviated Injury Scale (AIS) for grading the severity of injuries sustained in automobile accidents. This scale represents severity in terms of the following ten categories:

0. No injury.
1. Minor.
2. Moderate.
3. Severe (not life-threatening).
4. Severe (life-threatening, survival probable).
5. Critical (survival uncertain).
6. Fatal within 24 hours (fatal lesions of single region of body, plus injuries of other body regions of severity code 3 or less; fatal from burns regardless of degree).
7. Fatal within 24 hours (fatal lesions of a single region of body plus injuries of other body regions of severity code 4 or 5).
8. Fatal (2 fatal lesions in 2 regions of body).
9. Fatal (3 or more fatal injuries; incineration by fire).

Each injury category is characterized by examples of injuries particular to various body systems including "head and neck," "chest," "abdomen," "extremities and/or pelvic girdle" and "general" injuries. The examples listed under each category are rather specific but the investigators note that the injuries included "represent the vast majority of injuries any investigator is likely to see" (Committee on Medical Aspects of Automotive Safety, 1971, p. 280). However, in later research, the Committee notes that the AIS

tends to be too subjective and thus the criteria for rating injuries are not readily identifiable or reproduceable (1972, p. 717). Accordingly, the Comprehensive Injury Scale (CIS) was developed (1972, p. 717). The CIS is very complex and difficult to apply. It considers injury by medical specialty and scales severity with respect to energy dissipation, threat-to-life, permanent impairment, treatment period, and incidence. An adjustment for age is also included.

Kirkpatrick and Youmans (1971)

Kirkpatrick and Youmans' "trauma index" is similar to the SIMBOL rating system. It consists of a simple classification scheme based on easily measured parameters available at the scene of the accident and obtainable by non-physician personnel. These parameters were classified into five categories:

1. Region of body injured.
2. Type of injury.
3. Cardiovascular status.
4. Central nervous system status.
5. Respiratory status.

These categories were further divided into four graduations reflective of increasing severity (e.g., 'drowsy' to 'stupor' to 'motor or sensory loss' to 'coma' for central nervous system status). These grades of severity were arbitrarily[3] awarded scores of 1 (minimal), 3 (moderate), 4 (moderate), and 6 (severe) (1971, p. 711). This index was

[3]Scores of '2' and '5' were arbitrarily deleted to allow some numerical separation between minimal, moderate, and severe ratings.

shown to be well-correlated to severity (1971, p. 714).

Baker, O'Neill, Haddon, and Long (1974)

Baker et al. developed the Injury Severity Score (ISS) as an extension of the Committee on Medical Aspects of Automotive Safety's AIS as a method for assessing severity of multiple injuries. Specifically, the ISS is based on categories one through five of the AIS. The ISS was defined as "the sum of the squares of the highest AIS grade in each of the three most severely injured areas" of the body (1974, p. 190). This measure was shown to be reasonably correlated with mortality.

Semmlowe and Cone (1976) later confirmed the validity of the ISS. Specifically, a strong relationship between the ISS and mortality was demonstrated based on an analysis of 8,852 cases from the Illinois Trauma Registry.

Cowley, Sacco, Gill, Champion, Long, Copes, Goldfarb, and Sperrazza (1974)

Cowley et al. developed a "prognostic index for severe trauma" based on a selected set of physiological and biochemical measurements. This set of parameters included systolic blood pressure, hematocrit, fibrinogen, potassium, osmolality, and creatinine. The measured values of these parameters were combined into an index of severity using the mathematical concept of Euclidean Distance. This concept enables the values of the parameters to be expressed in terms

of their relative deviation from "normal."[4] Close correlations with physician assessment of prognosis and with survival were demonstrated.

Implications for the Present Research

Several significant conclusions can be drawn from this brief review of past patient outcome/severity research. The most obvious and important observation is that the relationships between EMS intervention, severity, and patient outcome is long overdue for intensive investigation. Specifically, with respect to outcome:

- Too much emphasis has been placed on death as an outcome.
- The disability/disfunction outcome measures, while being good indicators of long term outcomes, may not be strongly related to EMS intervention. Thus, a more appropriate and sensitive outcome measure is needed. Stabilization outcome appears to be a promising concept.
- The disability/disfunction measures are difficult to apply and are very time consuming. A simpler system of outcome measurement is needed.

And with respect to severity:

- It is both feasible and desirable to develop a numerical index of severity.
- The index of severity should be composed of easily measured and readily available information such as the indices of Williams and Schamadan (1969) and Kirkpatrick and Youmans (1974).

The present research considers the factors mentioned above and through the achievement of the objectives of the

[4]Euclidean Distance is further discussed on page 39.

thesis, develops an index of initial condition and a stabilization outcome measure.

CHAPTER III

SCOPE AND LIMITATIONS

The scope of the present research is limited to the development of two evaluative measures, an index of initial condition and a stabilization outcome measure. As previously described, the index of initial condition is a measure of severity of patient condition and the stabilization outcome measure is an indicator of the extent to which a patient's condition is "stabilized" as a result of emergency medical treatment. Both measures were developed for the specific medical emergency of acute myocardial infarction. Although the present application is condition-specific, it is hypothesized that the method of approach is valid for other conditions as well.

The following sections describe the scope and limitations of the study population and the method of data collection.

The Study Population

The population chosen for study was comprised of all patients discharged with a final diagnosis of acute myocardial infarction from a 400-bed general hospital[5] during the

[5]Since only one hospital was studied, it was not possible to determine the extent to which outcome is a function of the hospital at which the patient receives treatment and, ipso facto, the emergency department treatment protocol in that particular hospital.

period from January 1, 1975 to December 31, 1975. No attempt was made to verify the infarction.

Emergency cases were identified by specifying that each patient must have been transported to the hospital by an ambulance and admitted through the emergency room. Furthermore, only those cases handled by the county emergency medical service were included in the analysis.[6] As a result of this data selection process, a total of 93 cases was obtained.

It should be noted that these cases represent only part of the population of interest. This sample does not include those AMI patients who (1) used private transportation to the hospital, (2) experienced sudden death before arrival of an ambulance or (3) experienced an AMI in the hospital as a complication secondary to another complaint.

Data Collection

Information concerning the 93 cases was collected[7] on a retrospective basis from the ambulance run report (Appendix A), the emergency department report (Appendix C), and other hospital medical records. In general, the data describe

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[6]Several other ambulance providers accounted for a small proportion of the AMIs transported to the hospital during the study period. Rather than attempt to analyze the effect of this additional variable (i.e., ambulance company) based on a limited number of cases, only the major provider was included in the study.

[7]A special form was designed for the purpose of abstracting information from patient records (see Appendix B).

selected characteristics of the patient's episode of illness and past medical history. Specifically, due to the nature of the research, emphasis was centered on the pre-hospital phase of the illness. Accordingly, Tables 1 and 2 in Chapters IV and V, respectively, present the basic data sets on which the two models (the index of initial condition and the stabilization outcome measure) were based.

It should be noted that absolutely no information identifying individual patients, the hospital, or the physicians were recorded in the data collection process. These restrictions were necessary to assure confidentiality of patient records and did not limit the research in any manner whatsoever.

The Retrospective Approach

As previously noted, data were collected retrospectively from past patient records rather than prospectively in a specifically designed protocol. A prospective study is usually preferred for a number of reasons. Among these are:

1. Minimization of observer error--Observers can be trained in proper data collection methods. In a retrospective study, the investigator has no control over the quality of data recording.

2. Standardization of data collection methods--Instrumentation and equipment can be calibrated and checked for accuracy; observers can be trained to follow consistent decision rules in questions requiring judgment.

3. Collection of data that are not routinely available--Exacting data requirements suiting the particular research effort can be obtained.

On the other hand, prospective studies are usually costly and time-consuming. For these and other reasons, retrospective studies are often chosen by default. However, in the present case, the retrospective approach was chosen by design in order that the evaluative measures could be based solely upon presently available data. Such measures would have the advantage of being immediately useful in not only the community being examined, but in other areas as well, since almost all of the data collected are standard in most patient record-keeping systems.

Given that data are collected retrospectively, one must recognize the inconsistencies introduced by poor data quality. These inconsistencies compound the difficulties associated with the study of already "fuzzy" phenomena such as severity and outcome and thus represent a limitation of the models developed herein. However, there is value in determining the extent to which presently available data can be used to develop such evaluative models.

CHAPTER IV

DEVELOPMENT OF AN INDEX OF INITIAL CONDITION

As Peel et al. (1962, p. 745) expressed it so well:

> The wide variation in severity of cardiac infarction is well known. At one extreme the patient is admitted in severe irreversible shock, cold, clammy, and dazed with a rapid feeble pulse, low or perhaps immeasurable blood pressure, and widespread changes of severe degree in the cardiogram: his chances of surviving are indeed slender. At the opposite extreme is the patient with cardiac pain, perhaps felt only on effort, of good colour, without shock, or breathlessness, with normal pulse and blood pressure, and with limited cardiographic changes: such a patient is most unlucky if he does not survive the acute stage. Between these all possible graduations are met . . . It seemed to us that a numerical system might be devised that would express severity . . . .

It is on this rationale that an index of initial condition for AMIs is developed.

Coronary Prognostic Indices

Much can be learned toward the development of an index of initial condition for AMIs by examining the development of coronary prognostic indices (CPIs). CPIs provide a measure of severity of infarction very similar to the proposed index except that CPIs have been developed only for data measured on or after admission to the hospital. Hence, a brief review of CPIs follows.

Peel et al. (1962)

One of the first efforts which could be classified as a CPI was developed by Peel, Semple, Wang, Lancaster, and Dall in 1962. This index was based on a number of factors identified by the investigators through past experience as being important with respect to immediate prognosis. These factors are age, sex, previous cardiac history, degree and severity of shock, presence and severity of heart failure, cardiac rhythm, and the nature and extent of cardiographic signs.

An index of severity based on the above factors was empirically constructed by assigning a numerical "weight," or measure of importance, to each of the factors and summing the weights present for a particular patient to obtain a prognostic score. This score was demonstrated to be reflective of mortality.

The specific method by which this index was developed involved the following steps:

1. A weight was arbitrarily assigned to each factor based on the investigators' general clinical impression of its relative contribution to prognosis.

2. A series of patient cases was independently assessed by two physicians, and a score was calculated for each case. At the same time, weights were amended, and factor definitions were clarified as necessary to obtain consistency.

3. As a test for validity, scores were calculated for two additional sets of patients. The magnitude of the index with respect to mortality was then compared across the three groups of patients. Consistency was reasonably demonstrated.

4. The three series were combined in order to develop a partitioning of the index score associated with expected prognosis. The result was four categories in which mortality increased from three percent if the index is in the 1 to 8 range to 88 percent in the range above 20.

Hughes et al. (1963)

Hughes, Kalbfleisch, Brandt, and Costiloe (1963) developed a CPI using the method of linear discriminant analysis to statistically generate the factor weights. This method was selected because, unlike the method employed by Peel et al., it is objective and "allows for consistent quantification of each factor" included in the analysis. In addition, Hughes et al. note that discriminant analysis has been described as the method which most closely approximates the aggregation of clinical judgments (Overall and Williams, 1961).

The discriminant model was of the form $Z_j' = \sum_{j=1}^{p} x_{ij}B_{ij}$ where x_{ij} is the measured value of a particular variable i (for a total of p variables) for patient j and B_{ij} is the corresponding discriminant weight. Z_j' represents the predicted value of Z_j, where Z_j was defined as follows:

$$Z_j = \frac{\text{no. of survivors in the sample}}{\text{total no. of patients in the sample}}, \text{ if the patient survives.}$$

$$= \frac{\text{no. of non-survivors in the sample}}{\text{total no. of patients in the sample}}, \text{ if the patient dies.}$$

Since the values of Z_j and x_{ij} were known, the B_{ij} (weights) were calculated so as to yield maximum separation between the scores of survivors and non-survivors.

Variables (factors) included in the analysis were selected on the basis of their significance with respect to mortality. Both single variables and pairs of variables (reflecting interaction effects) were included. In all, fourteen different variables and eight interactions were chosen for inclusion.

Using the calculated weights, discriminant scores were computed for each of the patients in the sample. An optimum separation point of Z = +.23 was then found by minimizing the number of misclassifications (e.g., a non-survivor classified as a survivor, or vice versa, as indicated by the discriminant score). Thus, patients with scores of greater than +.23 are predicted to live and all others are predicted to die. Using this approach, a misclassification rate[8] of 83.3 per cent was obtained.

[8]The misclassification rates of the CPIs reviewed herein are compared in Table 32 (p. 115).

Shubin et al. (1968)

Shubin, Afifi, Rand, and Weil (1968) developed a CPI specifically for myocardial infarctions complicated by the presence of cardiogenic shock. The index was constructed using linear discriminant analysis and was based on hemodynamic measurements only. These parameters included systolic and diastolic blood pressure, appearance time, mean circulation time, cardiac index, stroke index, central blood volume, resistance, and pulse pressure. All were measured four hours prior to discharge or death.[9]

Discriminant functions were derived for all combinations of two and three variables (limited to no more than three variables due to the extremely small sample size of 20 patients). The "best" discriminant function (that which yielded the lowest probability of misclassification) was found to include diastolic blood pressure and stroke index and was computed as follows: Discriminant function score = .0166 (diastolic pressure) + .01852 (stroke index). This index was applied to a second set of patients with a correct misclassification rate of 93 per cent.

Norris et al. (1969)

Norris, Brandt, Caughey, Lee, and Scott (1969) developed a CPI which included age, position of infarct,

[9]The authors hypothesized that the values of the parameters would be most likely to show the greatest difference between survivors and non-survivors at this time.

admission systolic blood pressure, heart size, degree of lung field congestion, and history of previous ischemia. These variables were selected because each was shown to be independently related to mortality in preliminary analyses. A numerical index similar to that of Hughes et al. was constructed using linear discriminant analysis. Through the use of the resultant index, the sample of patients was divided into six sub-groups with increasing mortality from three to 78 per cent. Classification error was not assessed.

It should be noted that the discriminant analysis was applied in a manner somewhat different from the previously noted studies. Prior to application of the model, the data were coded in a manner reflective of mortality encountered in the preliminary analyses. For example, consider the variable, degree of lung congestion. If the lung fields were normal, the variable was coded as zero; if venous congestion was present, a code of .3 was assigned, interstitial edema was coded as .6, and pulmonary edema as 1.0.

Verdouw et al. (1975)

Verdouw, Hagemeijer, Dorp, van der Vorm, and Hugenholtz (1975) generalized the approach used by Shubin et al. as they developed a CPI based solely on hemodynamic parameters and valid for AMIs both with and without the presence of shock. This prospective study assessed the effects of heart rate (HR), systolic blood pressure (SP),

diastolic blood pressure (DP), pulmonary capillary pressure (PCW), and mixed venous oxygen saturation (MVO_2 sat) on survival two to three weeks after infarction.

Two prognostic indices were developed as a result of this study. The first was constructed by examining the differences in survivors and non-survivors with respect to the above variables and selected combinations, e.g., DP/PCW, MVO_2sat/PCW, (SP X MVO_2sat)/PCW, (DP X MVO_2sat)/PCW, (DP X MVO_2sat)/(PCW X HR) using the student's t-test. (DP X MVO_2sat)/PCW yielded the most significant difference ($p < .005$) between the two groups. Using this index, a misclassification rate of 9 per cent was obtained.

Linear discriminant analysis was also used to examine the discriminating power of the selected variables. The most powerful index consisted of .024(SP) + .217(PCW) + .234(MVO_2sat). Using this index, a misclassification rate of 10.7% was obtained.

Conclusions Drawn from Past CPI Research

The CPI of Peel et al. has the singular disadvantage of being based on subjective weightings and thus not easily reproduced. In addition, Peel's index, as well as that of Hughes et al., employ vague clinical terms such as "shock" and "congestive heart failure," the assessment of degree being open to considerable variation in interpretation. As Norris et al. (1969) have observed, these types of terms, if not rigidly defined, can lead to the development of

circular arguments in subsequent analyses. Also, inclusion of such judgmental variables may require that a physician only can adequately apply these indices.[10]

Conversely, the indices of Norris et al., Shubin et al., and Verdouw et al., while consisting of only objectively measured variables, include data that are not available in the prehospital phase of infarction. In addition, the Shubin index is overly restrictive for the purposes at hand since it only applies to cases of AMI complicated by cardiogenic shock.

Several conclusions directly related to development of the index of initial condition can be drawn from the preceding review of CPIs. These include:

1. A linear statistical model has been found to be appropriate for construction of a severity index for AMIs.

2. Linear models are widely used in this type of research.

3. Hemodynamic parameters have been found to be appropriate indicators of severity.

4. The type of approach employed by Norris et al. and Verdouw et al. appears to be applicable to the present research.

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[10]Such a requirement would be undesirable and probably infeasible for large-scale research efforts. In addition, variations among individual physicians would present problems.

Conceptual Development of the Index

In order to make valid inferences concerning the differences in stabilization outcomes of a given group of AMI patients, the characteristics of that population must initially be homogeneous. However, few patient populations are naturally homogeneous due to the immense number of patient and condition-specific variables to be accounted for (such as those noted in the previous section). Thus, when attempting to examine the outcome of a particular action on a given population, it is necessary to "control" the bias introduced by the characteristics of that population.

One way to eliminate, or minimize, this bias is to divide the population into sub-groups, where each sub-group is composed of patients with similar characteristics. Since we are interested in outcome, it follows that these sub-groupings should be structured in a manner so as to "factor-out" or control those characteristics that affect outcome. Insomuch as the characteristics of interest have an effect on outcome, they can be considered in terms of prognosis.[11]

Feinstein (1972) has formalized the above reasoning into a method known as prognostic stratification. As Feinstein (1972, p. 286) states:

> In order to remove or reduce the effects of prognostic heterogenity, the original cohort can be divided

[11] Prognosis can be defined as the "prediction of course and end of disease, and outlook based on it." (Taber, 1970)

> into sub-groups, or strata, of members who are similar in their prognostic expectations. The results of the therapeutic or other maneuvers are then compared within the same prognostic stratum. The division of cohort populations into prognostic strata that have different susceptibilities for the target event [outcome] is a scientific necessity of clinical epidemiologic research.

The nature and form of the initial condition classification can be further delineated by more precisely defining the relationship between initial condition and prognosis. To begin, due to the nature of the evaluation, it is necessary to represent patient condition prior to extensive emergency medical intervention. Accordingly, classification of initial condition can be thought of as a means of describing the degree of "severity" of a patient's illness, upon initial contact with the EMS system. The degrees of severity, of the levels of initial condition, are associated with estimates of short-term prognosis.[12]

Development of the Statistical Model

A multiple linear regression model was used to develop the index of initial condition. Conceptually, this model expresses the dependent variable, outcome, as a function of a number of independent variables.

The dependent variable, survival, is a dichotomous[13]

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[12]The initial condition classifications will be indicative of prognosis only in a static sense, as they are derived from a single measurement and are not based on examination of patient status over a period of time or after introduction of prescribed therapeutic maneuvers.

[13]The multiple linear regression model with a dichotomous dependent variable is equivalent to Hughes et al. (1963) discriminant analysis formulation.

indicator (patient lives or patient dies) of short term outcome and, in this instance, is measured at discharge from the hospital. For the typical AMI patient, the time interval involved is usually in the range of fifteen to thirty days after admission, providing that the patient survives. Hospital survival was selected over long-term mortality since this research is directed toward the immediate outcome of the acute emergency episode.

The independent variables can be divided into (1) predisposing and (2) episodic variables. Pre-disposing variables describe static characteristics of the patient which increase the patient's susceptibility to infarction. These variables include age, sex, weight, heart size, and previous patient history.[14] Although these variables are not generally associated with a particular episode of illness, each has been shown to have an effect on outcome.[15]

Episodic variables are direct measures of a patient's clinical status at a particular point in time. These variables include systolic blood pressure, pulse rate, respiration rate, pupil status and level of consciousness.

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[14]The information afforded by inclusion of the patient history variables is, of course, limited to those previous conditions that were appropriately diagnosed and entered into the patients' medical records. (For example, the effect of a previously undiagnosed infarction on severity of illness cannot be assessed in the model described herein.)

[15]See Peel et al. (1962), Hughes et al. (1963), Norris et al. (1969), Fulton et al. (1969), Chiang et al. (1970), McGuire and Kroll (1972), and Burggrat and Parker (1975).

Since it was desired to develop a severity index based on pre-hospital, pre-treatment information, the episodic variables included in the model were necessarily limited. This restriction, compounded by the limitations of retrospective data collection, limited the data available for inclusion in the model to that information contained within the ambulance run report (see Appendix A), which is the only pre-hospital data collection instrument presently available in the system under study.

Conversely, selection of the pre-disposing variables was not limited by the information available from pre-hospital sources since these variables are considered to be non-time dependent.

The basic data set on which the index was developed is shown in Table 1. Included are both pre-disposing and episodic variables and their corresponding codes. It should be noted that a number of "interaction" terms are also included (an interaction represents some interdependency between two or more variables).

In the present analysis, only selected interactions were considered. These interactions were chosen on the basis of known clinical relationships. For example, in cardiogenic shock, the interaction between blood pressure and pulse rate is well known. As the blood pressure falls to dangerously low levels, cardiac output decreases, and the pulse rate often becomes very rapid and "thready."

Table 1. Basic Data Set for the Index of Initial Condition

Variable	Symbol	Code
Age	AGE	(b)
Sex	SEX	0=male 1=female
Pupil Status[a]	PUPIL	0=equal 1=unequal 2=dilated 3=no response
Level of Consciousness[a]	CONS	0=normal 1=dazed 2=confused 3=unconscious
Weight	WT	0=not obese 1=obese
History of Previous Infarction[d]	HISTMI	0=no 1=yes
History of Previous Angina[d]	HISTANG	0=no 1=yes
History of Previous Hypertension[d]	HICDA	0=no 1=yes
History of Previous Diabetes[d]	HISTDIA	0=no 1=yes
History of Previous Congestive Heart Failure[d]	HISTCHF	0=no 1=yes
Heart Size[e]	SIZE	0=not enlarged 1=enlarged
Pulse Pressure[c] (ambulance)[a]	APP	(b)
Systolic Blood Pressure (ambulance)[a]	ASBP	(b)
Diastolic Blood Pressure (ambulance)[a]	ADBP	(b)
Pulse Rate (ambulance)[a]	APULS	(b)
Respiration Rate (ambulance)[a]	ARESP	(b)
Systolic Blood Pressure x Pulse Rate[a]	CROSS1	(b)
Diastolic Blood Pressure x Pulse Rate[a]	CROSS2	(b)
Pulse Pressure x Pulse Rate[a]	CROSS3	(b)

Table 1 (concluded)

Variable	Symbol	Code
Respiration Rate x Pulse Rate[a]	CROSS4	(b)
Respiration Rate x Pulse Pressure[a]	CROSS5	(b)
Euclidean Distance at Scene[a]	AEUCLID	(b)

[a]Measured on arrival of the ambulance on the scene (from the ambulance run report).

[b]No code required.

[c]Equal to systolic blood pressure minus diastolic blood pressure.

[d]Presence ascertained from the patient's history in the medical record.

[e]Verified by chest x-ray taken within 24 hours of admission in approximately 75 per cent of the cases.

One type of interaction that deserves special attention involves the concept of "Euclidean Distance." Previously Cowley et al. (1974, p. 1029) demonstrated the use of this concept in the evaluation of a trauma patient's clinical status, and as a result developed an index of severity. The Euclidean distance measurement allows one to express a value in terms of its derangement from normality. Briefly stated, Euclidean distance, $|E(\bar{a},\bar{b})|$, is defined for any two points, $\bar{a}$ and $\bar{b}$, in n-dimensional space, such that:

$$|E(\bar{a},\bar{b})| = [(a_1-b_1)^2 + (a_2-b_2)^2 + \ldots + (a_n-b_n)^2]^{1/2}$$

where, in the particular application reported here,

$\bar{a} = (a_1, a_2, \ldots, a_n)$ = measured physiological variables, and

$\bar{b} = (b_1, b_2, \ldots, b_n)$ = "normal" or "desired" values of the variables.

Cowley et al. observe that there is an "obvious disadvantage" to calculating the Euclidean distance between $\bar{a}$ and $\bar{b}$ as defined. They note that variables having high values and large variances usually dominate the distance measurement, although they may not be the most clinically significant. Accordingly, Cowley et al. suggest that the measurements be statistically normalized to facilitate the interpretation of clinically abnormal values.

In the present research, the values of each of the variables[16] were normalized as follows:

$$N_i = \frac{a_i - b_i}{\sigma_i}$$

where σ_i = measured standard deviation of variable i.

The $\bar{a}$ were defined as the values of measured physiological variables, specifically pre-treatment measurements of systolic blood pressure, diastolic blood pressure, pulse rate, and respiration rate. The $\bar{b}$ were defined as the values of the vital signs taken upon discharge from the hospital (for survivors only). Rather than relying on a single measurement, the average of the last four recorded values (usually measured during the final 24 hours of the hospital stay) was used.

The Mathematics

Mathematically, the regression model can be described as follows:[17]

$$Y_j' = B_0 + B_{1j}X_{1j} + B_{2j}X_{2j} + \ldots + B_{kj}X_{kj} + e_j$$

where Y_j' is the value of Y_j predicted by the regression

[16]The variables included in the measure are systolic and diastolic blood pressure, pulse rate, and respiration rate.

[17]To be found in any standard text on statistics.

equation and where,

Y_j = j^{th} observation on the dependent variable, hospital survival (the measured outcome at discharge from the hospital of patient j as a result of a particular acute emergency episode).

x_{ij} = j^{th} observation on independent variable i (measured values of a particular variable i, such as age or pulse rate for a particular patient j).

e_j = residual for observation j (random error present in the model).

B_{ij} = statistically fitted coefficient of regression corresponding to independent variable i ($i \geq 1$).

B_o = statistically fitted constant term.

i = 1, 2, ..., k independent variables.

j = 1, 2, ..., n cases.

The mathematical objective of the regression analysis is to solve for the B_{ij} that yield the "best" statistical "fit" to the data. This can be accomplished by specifying an error function for the given model and solving for the B_{ij} so as to minimize this error.

The appropriate measure of error to be minimized is known as the "least squares," or sum of squared error, function and is defined as:

$$L = \sum_{j=1}^{n} e_j^2 = \sum_{j=1}^{n} (Y_j - Y_j')^2$$

where Y_j' = value of Y_j predicted by the regression equation.

Taking partial derivatives of L with respect to the

B_{ij} and equating to zero yields p = k+1 normal equations. Assuming that the function is differentiable, simultaneous solution of the resulting p equations in terms of the p unknowns (B_0, B_{1j}, ..., B_{kj}) yields p least square estimates of the B_{ij}.

In practice, the above calculations are performed on a digital computer. Accordingly, a set of "packaged" computer programs were used to develop and analyze the model. Specifically, the REGRESSION subroutine of the Statistical Package for the Social Sciences (SPSS) program was used (Nie et al., 1975).

It should also be noted that for some types of research problems, it is appropriate to consider the independent variables on a one-by-one basis for inclusion in the model. In this case, independent variables are usually "entered" in the model on the basis of some pre-established statistical criterion. The criterion generally used is related to the degree to which particular independent variable "explains" the variation of the dependent variable, when the effects of all other independent variables are held constant (e.g., the partial correlation of independent variable i with respect to Y_j).

This inclusion procedure is used when "a researcher wishes to isolate a subset of available predictor independent variables that will yield an optimal prediction equation with as few terms as possible" (Nie et al.,1975). Certainly, this

feature is desirable for the index of initial condition as it will allow the index to be reduced to its simplest form.

The "stepwise" method[18] of inclusion was specifically used to select the appropriate subset of variables. Draper and Smith (1966, p. 172) consider this method to be the best of the variable selection procedures and recommend its use.

Analysis of the Model

The statistical properties of the regression model were analyzed in three stages. First, the usual statistical tests dealing with "significance of regression" were performed. Secondly, the model residuals[19] were examined in order to test the assumptions of the model. Thirdly, the predictive accuracy, or conversely the misclassification rate, of the model was calculated.

Testing for significance of regression involves testing the hypothesis that the regression coefficients are all equal to zero. Acceptance of this hypothesis indicates that no linear relationship exists between the independent variables and the dependent variable. This hypothesis can be represented as follows:

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[18] Readers unfamiliar with the specifics of this procedure are referred to Draper and Smith (1966).

[19] The model residuals are defined as the n differences $e_i = Y_i - \hat{Y}_i$, $i = 1,2,\ldots,n$ where Y_i is the observed value of the dependent variable and $\hat{Y}_i$ is the predicted value for Y_i obtained by use of the fitted regression equation (Draper and Smith, 1966, p. 86).

H_0: $B_{ij} = 0$, $\forall$ i (the hypothesis to be tested).

H_1: $B_{ij} \neq 0$ for at least one i (the alternative hypothesis).

The above hypothesis is tested using the F statistic. This quantity is composed of the ratio of the variation accounted for by the fitted model to the unexplained variation. Symbolically,

$$F_o = \frac{\text{(sum of squares attributable to the regression)}/k}{\text{(sum of squares attributable to residual variation)}/(n-k-1)}$$

$$= \frac{SS_{reg}/k}{SS_{res}/(n-k-1)}$$

where:

$$SS_{reg} = SS_{total} - SS_{res},$$

$$SS_{total} = \sum_{j=1}^{n} (Y_j - \bar{Y})^2,$$

and $$SS_{res} = \sum_{j=1}^{n} (Y_j - Y_j')^2.$$

The hypothesis is rejected if $|F_o| > F_{\alpha,k,n-k-1}$, where $F_{\alpha,k,n-k-1}$ is a tabulated value of the F-distribution for a given level of significance, α[20] and for given n and k. Alternately, one can refer to the F-distribution and determine the probability (α) of obtaining an F ratio greater than or equal to the test statistic, F_o.

Given that the regression is significant, it is helpful

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[20] In the present study, $\alpha = 0.05$ was used as the maximum acceptable probability for statistical significance.

to calculate the coefficient of multiple determination, R^2. This quantity is the square of the multiple correlation coefficient, R, and is defined as follows:

$$R^2 = \frac{SS_{total} - SS_{res}}{SS_{total}} = \frac{SS_{reg}}{SS_{total}}$$

R^2 can be interpreted as the proportion of the total variance of the dependent variable "explained" by the regression equation.

Residual analysis was performed to examine the validity of the error assumptions made in the regression model. Specifically, these assumptions are:

1. The errors are independent.
2. The errors have zero mean and a constant variance.
3. The errors follow a normal distribution.

As stated by Draper and Smith (1966, p. 86), "... if our fitted model is correct, the residuals should exhibit tendencies that tend to confirm the assumptions we have made, or at least, should not exhibit a denial of the assumptions." Accordingly, the residuals were plotted and visually examined for significant violations of the assumptions.

Finally, the internal predictive validity of the fitted model was assessed by calculation of the misclassification rate of the model.

CHAPTER V

DEVELOPMENT OF A MEASURE OF STABILIZATION OUTCOME

The primary clinical objective of the EMS system as defined in the present research is to stabilize the condition of the emergency victim. To assess the extent to which this objective is attained, a measure of stabilization outcome was developed.

Stabilization Defined

Stabilization can be defined in many different ways. Originally, Myrick (1974) defined stabilization as the point at which a patients' condition is no longer time dependent. The American Heart Association Committee on Cardio-Pulmonary Resuscitation and Emergency Coronary Care (1974, p. 860) defines it in terms of process variables:

1. Assuring effective ventilation, either spontaneous or assisted.
2. Maintaining a stable cardiac rhythm and effective circulation, utilizing drugs as indicated.
3. Maintaining a functioning ECG monitor and an intravenous lifeline.
4. Establishing and maintaining communications necessary for consultation, transportation, and admission to a continuing care facility.

However, for outcome evaluation, a condition-oriented

definition of stabilization is required, the reason for which will become more apparent later.

For the purposes of this study, a patient is defined as stable if:

1. Certain vital signs do not fall below minimum levels.

2. The patient's condition is not deteriorating at the point of measurement (e.g., upon entry to the emergency department).

3. The patient's condition after emergency procedures have been performed is improved or unchanged with respect to the patient's condition before treatment. The change in condition is to be measured in terms of vital signs.

A patient is defined as unstable if any one of the above conditions is not satisfied.

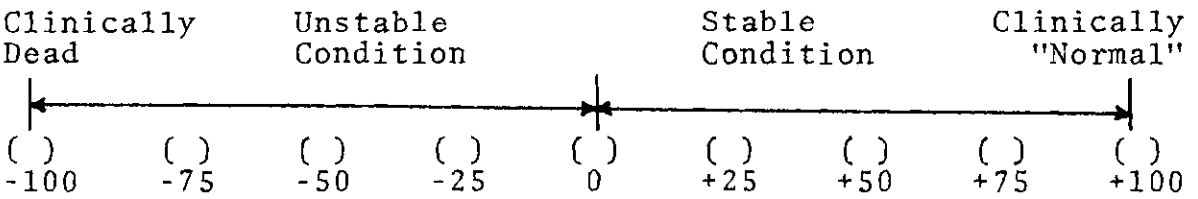
Stabilization, unlike severity, is intrinsically linked to the clinical response to emergency medical procedures. Ostensibly, without some type of stabilizing procedure, the condition of the "unstable" patient would deteriorate until death. Thus, stabilization is defined to represent the response to treatment in terms of the clinical manifestations of the illness episode. In order to represent this response, stabilization must be based upon dynamic measurements and is therefore measured over an interval of time (from measurements made in the ambulance to

measurements made in the emergency room).[21]

The distinction between severity and stabilization can be conceptually viewed as the difference between scalar and vector quantities. Severity, a scalar measurement, has only magnitude (in terms of degree of severity), whereas stabilization, a vector measurement, has both magnitude and direction (in terms of magnitude of change of physiological variables).

The Stabilization Outcome Scale

In order to measure the degree to which a patient is stabilized after EMS intervention, a stabilization outcome scale was developed. Conceptually, this scale can be interpreted as consisting of a number of different "levels of stabilization" and is represented by the following continuum:



As indicated, this scale consists of three primary

[21]Given the concept of stabilization based on change in condition over time (in addition to level of condition at a particular point in time), it would have been desirable to include some explicit consideration of prognosis (as defined as the probabilities of changes in condition over a specified period of time) in the definition of stabilization. However, in the interest of providing the panels of physicians with a simple operational definition of stabilization, prognosis was not explicitly addressed.

states: death (-100), stable (0), and normal (+100). Points between these states represent either unstable (-25, -50, -75) or stable conditions (+25, +50, +75).

Obviously, clinical death, and to lesser extent, normal, are reasonably well-defined states. Whereas death is represented by nil parameter values, normal, as defined herein, is represented by ranges of values for various physiological parameters considered to be typical for a "healthy" patient. However, stable versus unstable is a conceptual classification that is implicit within the mind of the physician. Thus, in order to aid in the demarcation of a stabilization scale, the relationships between a physician's subjective classifications and the objective physiological data must be quantified. Such is the purpose of the following stabilization outcome model.

Development of the Stabilization Model

The relationship between the physician's perception of level of stabilization and patient condition was formulated as a multiple linear regression model. Specifically, this model expresses the dependent variable, stabilization outcome, as a function of a number of independent variables representing the level of and change in a patient's clinical status as measured upon entry of the patient into the emergency department.

The independent variables primarily consist of vital

signs[22] (i.e., systolic and diastolic blood pressure, pulse rate, and respiration rate). In addition, age and sex are also considered.[23] It should be noted that the variables on which the model is based were necessarily limited to that information which is common to both the ambulance run report and the emergency department report (see Appendix C). This data limitation was necessary since the change in patient condition is of interest and hence, both pre-treatment and post-treatment measurements on the same variables must be made.

Interaction terms, including the previously described Euclidean distance, were also included in the model. These as well as the other independent variables are listed in Table 2.

Quantification of the Dependent Variable

As defined, the dependent variable, level of stabilization, is based on the physician's perception of status. An expert panel of clinicians was utilized to generate these

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[22] In the stabilization model, vital signs are measured on the scene and upon arrival at the emergency department.

[23] Information on race was also collected but was not included in the model. As subsequently discussed, the number of variables that could be included in the model was limited due to the small sample size (20). Since the investigator was not aware of any strong clinical evidence suggesting race as a correlate of outcome, it was omitted from the model. In addition, it would have been difficult to assess the significance of race given that 95 percent of the sample was white.

Table 2. Basic Data Set for the Stabilization Outcome Model

Variable	Symbol
Age	AGE
Sex	SEX
Pulse Pressure (ambulance)[a]	APP
Pulse Pressure (Emergency department)[b]	EPP
Systolic Blood Pressure (ambulance)[a]	ASBP
Systolic Blood Pressure (emergency department)[b]	ESBP
Diastolic Blood Pressure (ambulance)[a]	ADBP
Diastolic Blood Pressure (emergency department)[b]	EDBP
Pulse Rate (ambulance)[a]	APULS
Pulse Rate (emergency department)[b]	EPULS
Respiration Rate (ambulance)[a]	ARESP
Respiration Rate (emergency department)[b]	ERESP
Systolic Blood Pressure X Pulse Rate[a]	CROSS1
Systolic Blood Pressure X Pulse Rate[b]	CROSS6
Diastolic Blood Pressure X Pulse Rate[a]	CROSS2
Diastolic Blood Pressure X Pulse Rate[b]	CROSS7
Pulse Pressure X Pulse Rate[a]	CROSS3
Pulse Pressure X Pulse Rate[b]	CROSS8
Respiration Rate X Pulse Rate[a]	CROSS4
Respiration Rate X Pulse Rate[b]	CROSS9
Respiration Rate X Pulse Pressure[a]	CROSS5
Respiration Rate X Pulse Pressure[b]	CROSS10
Euclidean Distance at Scene[a]	AEUCLID
Euclidean Distance at Emergency Department[b]	EEUCLID

[a]Measured on arrival of the ambulance on the scene.

[b]Measured on arrival of the ambulance at the emergency department.

perceptions. An experiment was designed to quantify these perceptions.

The Delphi Technique. In order to most effectively utilize the information contained within the panel and to conserve the experts' time, a structured group opinion method known as the Delphi technique was used. The Delphi technique employs questionnaires to obtain information from a group of individuals. After the questionnaires are completed, individual responses are combined and a "group response" is compiled. Subsequently, this group response and any pertinent comments from individuals are "fed back" to the individuals together with a second questionnaire. Given the new information, individuals are requested to revise or refine their previous responses. The objective is to obtain agreement among the group of individuals.

The originators of Delphi (Dalkey, Helmer, et al., of the RAND Corporation), argue that it differs considerably from conventional face-to-face group situations in that it replaces direct confrontation and debate with a carefully contrived decision-making environment (Brown, 1968, p. 3; Dalkey and Helmer, 1963, p. 458).

This environment is characterized by the following features (Dalkey, 1967, p. v):

(1) Anonymous response--Opinions of members of the group are obtained by formal questionnaire and no contact between the respondents is permitted.

Typically questionnaire administration is handled through the mail.

(2) Iteration and controlled feedback--Interaction is effected by a systematic exercise conducted in several iterations, with carefully controlled feedback, in terms of the group response, between rounds ("rounds" are successive sets of questionnaires).

(3) Statistical group response--The group opinion is represented by an "appropriate" statistical measure, such as the median or mean.

Dalkey further reasons that the above special features of Delphi reduce the undesirable effects of group interaction. Specifically, he cites the negative effects of the socially dominant individual (due to the personality type, status, etc.), group pressure for conformity, and "semantic noise."[24] Helmer and Rescher (1959) note that Delphi "eliminates committee activity altogether, thus further reducing the influence of certain psychological factors, such as specious persuasion, the unwillingness to abandon publicly expressed opinions, and the bandwagon effect of majority opinion." These and other disadvantages of face-to-face interaction are more fully documented by Maier (1967) and

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[24]"Semantic noise" is defined as "irrelevant or redundant material that obscures the directly relevant material offered by the participants" (Dalkey, 1967, p. 3).

Asch (1950).

In addition to minimizing some of the detrimental aspects of group processes, it appears that Delphi offers many of the advantages commonly associated with interacting groups including:

(1) Greater number of approaches to a problem.

(2) Greater amount of knowledge and information available.

(3) Increased acceptance and comprehension of solutions generated by the group due to participation (Maier, 1967, p. 316).

The special restrictions inherent to Delphi (anonymity, controlled feedback, statistical response), do not alter the fact that a group is still represented in the process. This resource remains unchanged--only the method by which it is utilized differs. In fact, due to the unique structure of the Delphi, most of the barriers to equal participation are eliminated and, therefore, the above characteristics are probably enhanced.

Maier (1967) cites disagreement, conflicting versus mutual interest, time requirements, and position shifts as being critical factors serving as either group assets or liabilities depending greatly on the skill of the group leader. The skillful group leader manages the group in such a way as to capitalize on these factors. Delphi suffers in this respect because it functions without a leader. However, the experimenters have some control over the group by appropriately filtering feedback information.

In addition to the preceding theoretical concerns, several considerations of a practical nature indicate a preference for Delphi. First, Delphi can be considered as superior to other group processes with respect to cost. Often, this factor alone is the critical consideration. Other factors which tend to reinforce a preference for Delphi include:

1. Geographically dispersed participants.
2. Panelists with only a limited amount of time available to participate in an experiment. This would be especially common when one is dealing with experts. Such limited time also might be in relatively short scattered segments.
3. Participants not all available to convene at the same time. This factor, of course, becomes more of a problem as group size increases.

In the present research, the first factor above was of limited concern since all of the participants were obtained from within the approximately 30 mile radius of the metropolitan Atlanta area. However, the second and third considerations were of paramount importance.

Other Relevant Parameters. A review of group decision-making literature shows that a number of other factors other than the type of group process can have an impact on group effectiveness. Filley (1970, p. 327) in an exposition on committees, has suggested that these factors include group

size, management, and composition. Fortunately, these factors are controllable to some extent. Concerning group size, small group research (Filley, 1970, p. 329; van de Ven, 1974, p. 21) has indicated that group size should be minimized (if the selected members possess sufficient knowledge and skills to solve the problem at hand) in order to yield the group more manageable. However, such research has generally dealt with face-to-face groups, not Delphi. With Delphi, individual group members do not respond to a number of other individuals but rather respond to a statistical representation of group opinion, thereby affording Delphi capable of handling larger groups. Notwithstanding this observation, a group size of six[25] was selected for use in the present study due to time and resource limitations.

Given this line of reasoning, group management is not explicitly applicable in a non-interacting group process such as Delphi. However, if the process is to run smoothly and without confusion, the questionnaires must be carefully designed. In the construction of the questionnaires, the experimenter acts as an artificial "group leader" and provides some aspects of management.

With regard to group composition, two factors must be considered--(1) cooperative versus competitive and (2) homogenous versus heterogenous. In general, cooperative

[25]Actually, a total of twelve participants were required since two panels were ultimately used in the experiment.

groups are preferred (although this characteristic has no overt effect in Delphi groups). The question of homogeneity or heterogeneity is less clear. However, it has been suggested that there is value in using a heterogeneous group if its negative effects can be controlled (Filley, 1970, p. 336). In the present research, diversity in background pertinent to the various aspects of the clinical management of AMI was considered to be of great importance.

In general, the composition of panels used in the present research could be described as cooperative and heterogeneous. As shown in Table 3, a number of specialties and sub-specialties are represented in the panels. The negative effects of this heterogeneity were not considered to be applicable since the individual panel members do not directly interact with each other.

The Delphi Experiment. The Delphi experiment was designed and conducted over two rounds.[26] Two panels of physicians participated in the experiment. The panels were selected so as to provide a measure of inter-panel validity of the results (see page 63). Both panels consisted of a mix of emergency department physicians and cardiovascular specialists. Judging from the specialties and types of

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[26]Theoretically, Delphi continues to iterate through successive rounds until consensus is obtained. However, due to time limitations and the desire to avoid "panel fatigue" (see Starkweather, 1975), the process was planned for two rounds only.

Table 3. Panel Composition

Panel	Age	Specialty	Sub-Specialty	Type of Practice	Years in Practice
#1	33	Internal Medicine	Emergency Medicine	Emergency Dept.	2
#1	33	Emergency Medicine	---	Emergency Dept.	4
#1	49	Internal Medicine	---	Private	22
#1	33	General Practice	---	Emergency Dept.	5
#1	36	Internal Medicine	Cardiology	Private	9
#2	47	Internal Medicine	Cardiology	Private	17
#2	35	Emergency Medicine	---	Emergency Dept.	10
#2	32	General Practice	Public Health	Emergency Health	5
#2	57	Cardiology	---	Private	30+
#2	34	Surgery	Emergency Medicine	Emergency Dept.	8
#2	29	Emergency Medicine	---	Emergency Dept.	1

practices represented in each of the panels it was initially assumed that the panels were equivalent in terms of expertise. However, as shown in Table 3 this assumption may have been incorrect if expertise is considered to be represented by the panelists' age and years in practice (i.e., Panel #2 appears to be "older" than Panel #1 and also includes more experienced physicians).

The first set of questionnaires (see Appendix D) were personally delivered to each of the physicians so that the concepts of the experiment could be explained in detail and questions answered without delay. Each panel member was asked to complete the questionnaire within a week, if at all possible.

Round one presented the panel with a sample of 20 cases[27] and requested that each be classified according to level of stabilization (based on the definition given on page 47) and recorded on the stabilization outcome scale. In addition, each participant was asked to briefly note the reason for classification of a patient at a particular level of stabilization.

Discussions with several of the panel members revealed

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[27]The 20 cases represent a random sample from the 93 case data base for the study. The sample was stratified with respect to survivors and non-survivors in the same proportion as contained in the overall sample. This number was not statistically selected but was considered to be a reasonable number of cases for the panel to work with.

that the stabilization outcome scale as originally conceived was subject to some misinterpretation. Accordingly, the scale was slightly modified to help improve its interpretation. (Note: The "final" scale is the one shown on page 48. The "original" scale is shown on page 137 as part of the round one questionnaire).

Between rounds one and two, the results from each panel were summarized and a second questionnaire designed (see Appendices E and F). This questionnaire was aimed toward reassessment of the previous responses in an effort to obtain consensus[28] among the panel.

Round two incorporated the improved stabilization outcome scale and further delineated its interpretation as shown in Table 4. As previously noted, the second questionnaire requested that each panelist reassess his previous response to each case in light of the corresponding group responses.

Group response was represented in terms of the low and the high response for each case, in addition to selected representative comments. The comments were identified as originating from either "low", "high" or "other" (between the

[28]Prior to the administration of the first questionnaire, consensus was defined in terms of the "truncated range." The truncated range is computed by taking the difference between the highest and lowest response for a particular patient case, after elimination of the pair of initial highest and lowest responders. Thus, consensus was a priori defined as a truncated range of less than or equal to 50 points on the stabilization scale, which extends from -100 to +100, a range of 200 points.

Table 4. Interpretation of the Stabilization Outcome Scale

Level of Stabilization	Interpretation
+100	Patient stabilized--condition clinically normal.
+75 +50 +25	Patient stabilized--all three of the conditions for stabilization are satisfied--intermediate levels of stabilization--the higher the rating, the better the prognosis.
0	Patient barely stabilized--lowest level of condition for a stable patient--patient questionably stabilized.
-25 -50 -75	Patient unstable--one or more of the three conditions for stabilization are not satisfied--the lower the rating, the worse the prognosis.
-100	Patient clinically dead.

two) responders.

Finally, as part of the second questionnaire, several items of supplemental information were obtained. This included assessments of each physician's degree of confidence in his estimates of stabilization and the degree of satisfaction with the stabilization concept, as well as comments on the approach in general.

The Mathematics. Mathematically, the multiple linear regression model can be described as follows:

$$Y'_j = B_0 + B_{1j}X_{1j} + B_{2j}X_{2j} + \ldots + B_{kj}X_{kj} + e_j$$

where Y'_j is the value of Y_j predicted by the regression equation and where,

Y_j = j^{th} observation on the dependent variable, level of stabilization.

X_{ij} = j^{th} observation on independent variable i.

e_j = residual for observation j.

B_{ij} = statistically fitted coefficient of regression corresponding to independent variable i ($i \geq 1$).

B_0 = statistically fitted constant term.

i = 1,2,...,k independent variables.

j = 1,2,...,n cases.

Again the B_i were computed by the method of least squares, the stepwise method of variable selection was employed; and the SPSS programs were used in the analysis.

Analysis of the Model

The regression model was analyzed with respect to internal statistical validity. Also, the estimates of the value of the dependent variable, level of stabilization, as generated by the two panels were analyzed with respect to inter-panel validity.

Analysis of Internal Validity

Internal validity was assessed in two stages. First, the significance of regression was tested using the F-test, and the coefficient of multiple determination was computed. Secondly, the residuals were analyzed to determine if any of the error assumptions had been violated.

Analysis of Inter-Panel Validity

Two panels were used to generate independent estimates of the levels of stabilization of the twenty patient cases. After the final consensus scores were computed for each case as assessed by each of the panels, the paired t-test was used to compare the scores of the two groups to determine if a significant difference existed between the corresponding two sets of estimates. This t-test entails testing of the following hypothesis:

$$H_0: \quad \delta = 0$$
$$H_1: \quad \delta \neq 0$$

where δ is the true mean difference between the groups with

sample mean, $\bar{d} = [\sum_{j=1}^{n} (X_{1j}-X_{2j})]/n$ and where the X_{1j} and X_{2j} are the responses for Panels #1 and #2, respectively. The null hypothesis, H_0, is tested against the alternative hypothesis, H_1, using the following test statistic:

$$t_o = \frac{\bar{d}-\delta}{s_{\bar{d}}}$$

where:

n = number of pairs = 20,

$s_{\bar{d}}$ = the sample standard deviation of $\bar{d}$,

$$= [(s_1^2 + s_2^2 - \frac{2\sum_{j=1}^{n} X_{1j}X_{2j}}{n-1})/n]^{1/2}$$

s_1 = the sample standard deviation of X_{1j},

s_2 = the sample standard deviation of X_{2j}.

The hypothesis is rejected if $|t_o| > t_{\alpha/2,n-2}$; where t is a tabulated value from the t-distribution for a given level of significance α.[29]

[29]In the present research, $\alpha = 0.05$ was used.

CHAPTER VI

RESULTS

This chapter presents the results of the development of the index of initial condition and the stabilization outcome measure. In summary, both models were found to be reasonably valid.

The Index of Initial Condition

The basic data set (see Table 1) on which the index was developed was refined to include several variations for detailed analysis. The refinements dealt exclusively with alternative representations of vital signs in the regression equations. The main effects due to vital signs were considered in terms of (1) individual "raw" measurements and (2) individual squared values. Also, as indicated previously, interactions between vital signs were represented as (1) cross products between selected pairs of vital signs and (2) the Euclidean distance. Accordingly, four distinct alternative regression models were developed based on combinations of the above variations in conjunction with the remaining variables in the basic data set. The four alternatives are hereafter referred to as Models A, B, C, and D, respectively.

The variables initially included in each model are

listed in Table 5. The variables entered and removed from the equations as a result of the stepwise selection procedure are listed in Tables 6, 7, 8, and 9. Also presented in Tables 6 through 9 are the significance of regression, the coefficient of multiple determination (R^2), and the coefficient of multiple correlation (R) at each stage of the procedure. Table 10 lists the resulting regression equations.

Figures 1, 2, 3, and 4 illustrate the derivation of the theoretical and optimized misclassification rates. The theoretical misclassification rate was calculated by classifying survivors as those cases with a regression score, or estimate, of 0.5 or greater (i.e., the probability of survival is greater than or equal to 0.5). The optimized misclassification rate was determined heuristically so as to minimize misclassification. This heuristic method involved calculation of the misclassification rates at all possible separation points (i.e. the point at which survivors are distinguished from non-survivors) accurate to 0.01 on the zero to one scale. Accordingly, the optimized rate was defined in terms of the separation point which minimized misclassification.

Internal Validity

The internal statistical properties of the regression models were assessed in order to (1) determine if the models adequately represent the phenomenon under study (i.e., predict AMI mortality) and (2) select the "best" model from

Table 5. Variables Initially Included in the Index of Initial Condition Model

Variable	Regression Model			
	A	B	C	D
AGE	X	X	X	X
SEX	X	X	X	X
PUPIL	X	X	X	X
CONS	X	X	X	X
WT	X	X	X	X
HISTMI	X	X	X	X
HISTANG	X	X	X	X
HICDA	X	X	X	X
HISTDIA	X	X	X	X
HISTCHF	X	X	X	X
SIZE	X	X	X	X
APP	X	X	X	X
ASBP	X		X	
ADBP	X		X	
APULS	X		X	
ARESP	X		X	
$(ASBP)^2$		X		X
$(ADBP)^2$		X		X
$(APULS)^2$		X		X
$(ARESP)^2$		X		X
CROSS1	X	X		
CROSS2	X	X		
CROSS3	X	X		
CROSS4	X	X		
CROSS5	X	X		
AEUCLID			X	X

Table 6. The Index of Initial Condition--Model A

Step	Variable Entered	Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	ADBP		16.30487	.000	.40935	.16756	16.30487	.000
2	SIZE		3.92932	.051	.45446	.20654	10.41192	.000
3	PUPIL		2.95816	.089	.48495	.23518	8.09724	.000
4	HISTANG		2.20787	.141	.50619	.25623	6.71775	.000
5	HISTCHF		2.97632	.089	.53283	.28391	6.10563	.000
6	HICDA		2.18613	.143	.55130	.30393	5.53076	.000
7	HISTDIA		1.41553	.238	.56287	.31682	4.96879	.000
8	CROSS5		1.47988	.228	.57465	.33022	4.56049	.000
9	ARESP		.81214	.370	.58102	.33759	4.13372	.000
10	CROSS3		1.51438	.222	.59265	.35123	3.89800	.000
11	WT		.89569	.347	.59943	.35932	3.61993	.000
12	SEX		.47094	.495	.60299	.36360	3.33279	.001
13	APULS		.49144	.486	.60671	.36810	3.09187	.001
14	AGE		.39911	.530	.60974	.37179	2.87453	.002
15	HISTMI		.17689	.675	.61110	.37344	2.66221	.003
16	APP		.12075	.729	.61203	.37458	2.47061	.005
17	CROSS4		1.36709	.247	.62247	.38747	2.41863	.006
18	CROSS1		.17660	.676	.62382	.38915	2.26514	.009
19	CONS		.01012	.920	.62390	.38925	2.11326	.014

Table 7. The Index of Initial Condition--Model B

Step	Variable Entered	Variable Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	CONS		15.41409	.000	.39984	.15987	15.41409	.000
2	SIZE		4.70320	.033	.45445	.20652	10.41100	.000
3	HICDA		4.06581	.047	.49534	.24536	8.56192	.000
4	HISTANG		1.87956	.174	.51295	.26312	6.96282	.000
5	HISTCHF		1.75577	.189	.52872	.27955	5.97539	.000
6	PUPIL		2.40077	.125	.54919	.30161	5.47020	.000
7	HISIDIA		1.49780	.225	.56150	.31528	4.93343	.000
8	CROSS5		1.48408	.227	.57336	.32874	4.53012	.000
9	CROSS4		1.77332	.187	.58708	.34466	4.26589	.000
10	WT		.87822	.352	.59377	.35256	3.92072	.000
11	APP		.77493	.382	.59962	.35955	3.62360	.000
12	APULSQ		2.74867	.102	.61947	.38375	3.63249	.000
13		CONS	.00289	.957	.61945	.38372	4.01890	.000
14	AGE		.41334	.522	.62237	.38734	3.68800	.000
15	HISTMI		.41110	.524	.62528	.39097	3.40729	.000
16	SEX		.26303	.610	.62715	.39332	3.14890	.001
17	CROSS3		.29355	.590	.62926	.39596	2.92801	.001
18	ARESPSQ		.08845	.767	.62990	.39677	2.71320	.002
19	CROSS1		.06051	.806	.63034	.39733	2.52081	.004
20	ADBPSQ		.12982	.720	.63131	.39855	2.35610	.006
21		CROSS3	.00094	.976	.63130	.39854	2.53358	.004
22	ASBPSQ		.02321	.879	.63148	.39876	2.35816	.006
23	CONS		.01449	.905	.63158	.39890	2.20041	.010

Table 8. The Index of Initial Condition--Model C

Step	Variable Entered Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	ADBP	16.30487	.000	.40935	.16756	16.30487	.000
2	SIZE	3.92932	.051	.45446	.20654	10.41192	.000
3	PUPIL	2.95816	.089	.48495	.23518	8.09724	.000
4	HISTANG	2.20787	.141	.50619	.25623	6.71775	.000
5	HISTCHF	2.97632	.089	.53283	.28391	6.10563	.000
6	HICDA	2.18613	.143	.55130	.30393	5.53076	.000
7	HISTDIA	1.41553	.238	.56287	.31682	4.96879	.000
8	AEUCLID	1.06085	.306	.57138	.32648	4.48382	.000
9	AGE	.74419	.391	.57730	.33328	4.05453	.000
10	WT	.51343	.476	.58138	.33800	3.67610	.001
11	HISTMI	.50243	.481	.58536	.34265	3.36449	.001
12	APULS	.24492	.622	.58732	.34494	3.07172	.002
13	ASBP	.41600	.521	.59065	.34887	2.84378	.003
14	CONS	.20725	.650	.59232	.35085	2.62512	.004
15	SEX	.15892	.691	.59362	.35238	2.43040	.007
16	ARESP	.01673	.897	.59376	.35255	2.24611	.011

Table 9. The Index of Initial Condition--Model D

Step	Variable Entered Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	CONS	15.41409	.000	.39984	.15987	15.41409	.000
2	SIZE	4.70320	.033	.45445	.20652	10.41100	.000
3	HICDA	4.06581	.047	.49534	.24536	8.56192	.000
4	HISTANG	1.87956	.174	.51295	.26312	6.96282	.000
5	HISTCHF	1.75577	.189	.52872	.27955	5.97539	.000
6	PUPIL	2.40077	.125	.54919	.30161	5.47020	.000
7	HISTDIA	1.49780	.225	.56150	.31528	4.93343	.000
8	APP	.97245	.327	.56935	.32416	4.43672	.000
9	HISTMI	.51281	.476	.57348	.32888	3.97477	.000
10	APULSQ	.34908	.556	.57629	.33212	3.58030	.001
11	WT	.51526	.475	.58045	.33693	3.27975	.001
12	AGE	.44312	.508	.58404	.34110	3.01978	.002
13	SEX	.30903	.580	.58655	.34404	2.78375	.003
14	AEUCLID	.18406	.669	.58805	.34581	2.56749	.005
15	ASBPSQ	.30106	.585	.59054	.34873	2.39176	.008
16	ARESPSQ	.04109	.840	.59088	.34914	2.21275	.013

Table 10. Alternative Regression Equations for the Index of Initial Condition

Regression Model	Regression Equation
A	$.93231332-.37269797\times10^{-2}(AGE)-.63156585\times10^{-1}(SEX)$ $-.97905029\times10^{-1}(PUPIL)+.82876572\times10^{-2}(CONS)$ $-.43875128\times10^{-1}(WT)+.53859634\times10^{-1}(HISTMI)+.22082484(HISTANG)$ $-.23370858(HICDA)+.21103879(HISTDIA)-.23832025(HISTCHF)$ $-.18482873(SIZE)+.11117119\times10^{-1}(APP)+.35636436\times10^{-2}(ADBP)$ $-.54934058\times10^{-2}(APULS)+.62377253\times10^{-2}(ARESP)$ $-.32053478\times10^{-4}(CROSS1)+.48328909\times10^{-4}(CROSS3)+.41584301\times10^{-3}(CROSS4)$ $-.73735074\times10^{-3}(CROSS5)$
B	$.90898826-.29340317\times10^{-2}(AGE)-.70188719\times10^{-1}(SEX)-.95511365\times10^{-1}(PUPIL)$ $+.92552756\times10^{-2}(CONS)-.41233613\times10^{-1}(WT)+.33169761\times10^{-1}(HISTMI)$ $+.20363073(HISTANG)-.23185094(HICDA)+.19703264(HISTDIA)$ $-.22179818(HISTCHF)-.19189452(SIZE)+.10693866\times10^{-1}(APP)$ $+.39882521\times10^{-5}(ASBPSQ)-.18218993(ADBPSQ)-.62909233\times10^{-4}(APULSQ)$ $+.24606777\times10^{-3}(ARESPSQ)+.27921005\times10^{-4}(CROSS1)+.43306560\times10^{-3}(CROSS4)$ $+.43306560\times10^{-3}(CROSS5)$

Table 10 (concluded)

Regression Model	Regression Equation
C	$1.1897377-.33222559\times10^{-2}(AGE)-.42914838\times10^{-1}(SEX)-.11397981(PUPIL)$ $-.34898121\times10^{-1}(CONS)-.43821033\times10^{-1}(WT)+.45208800\times10^{-1}(HISTMI)$ $+.19106587(HISTANG)-.26857697(HICDA)+.17758092(HISTDIA)$ $-.25398435(HISTCHF)-.15995565(SIZE)-.17348003\times10^{-2}(ASBP)$ $+.25574432\times10^{-2}(ADBP)+.18169332\times10^{-2}(APULS)-.11680859\times10^{-2}(ARESP)$ $-.96021811\times10^{-2}(AEUCLID)$
D	$1.3164995-.32250282\times10^{-2}(AGE)-.4628875\times10^{-1}(SEX)$ $-.12048357(PUPIL)-.37765213\times10^{-1}(CONS)-.39477174\times10^{-1}(WT)$ $+.44003866\times10^{-1}(HISTMI)+.18815649(HISTANG)-.27147947(HICDA)$ $+.18055047(HISTDIA)-.26450459(HISTCHF)-.15698781(SIZE)$ $-.24182605\times10^{-2}(APP)+.39233381\times10^{-5}(ASBPSQ)+.97692322\times10^{-5}(APULSQ)$ $-.39237068\times10^{-4}(ARESPSQ)-.20376221\times10^{-1}(AEUCLID)$

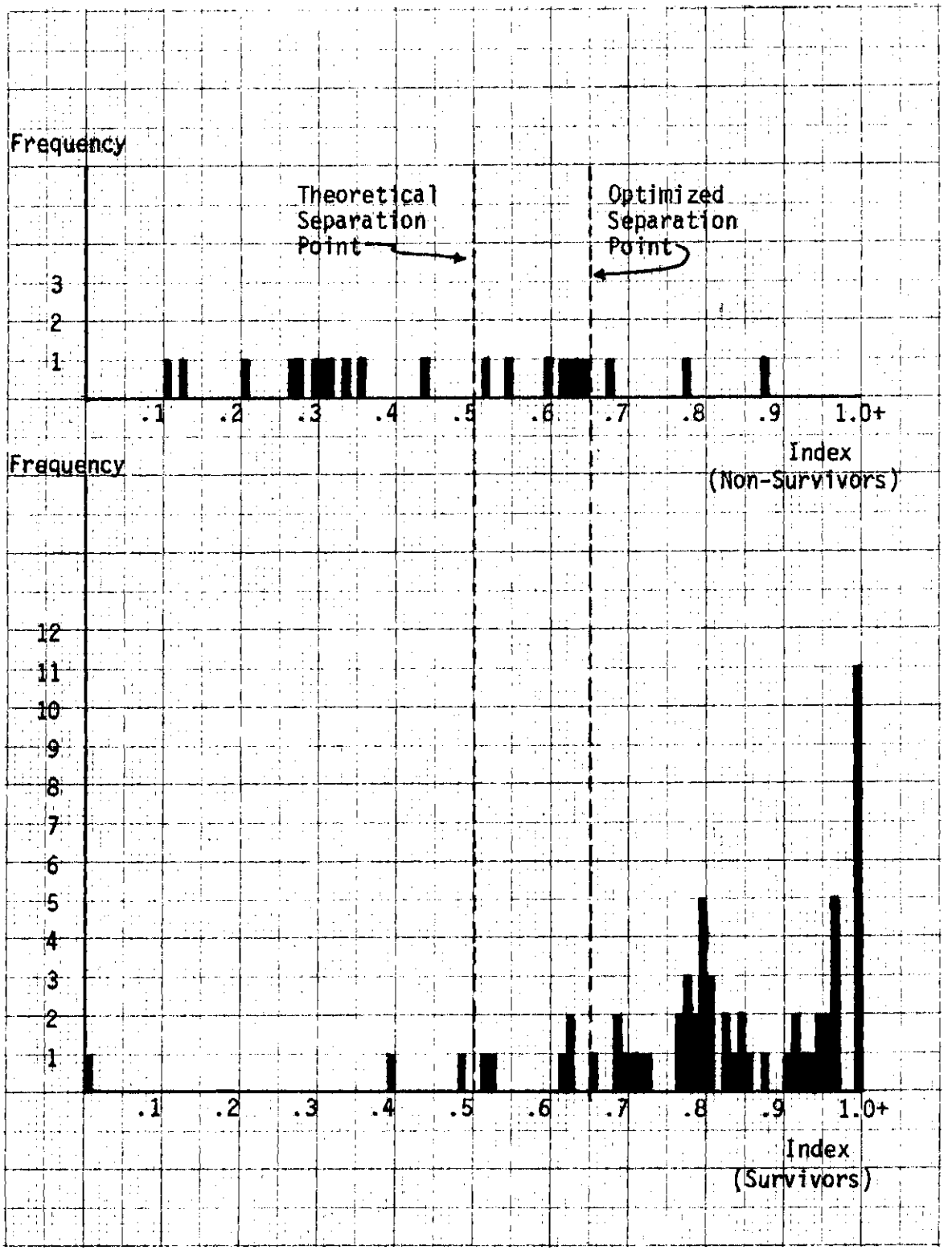

Figure 1. Misclassification Rates--Model A

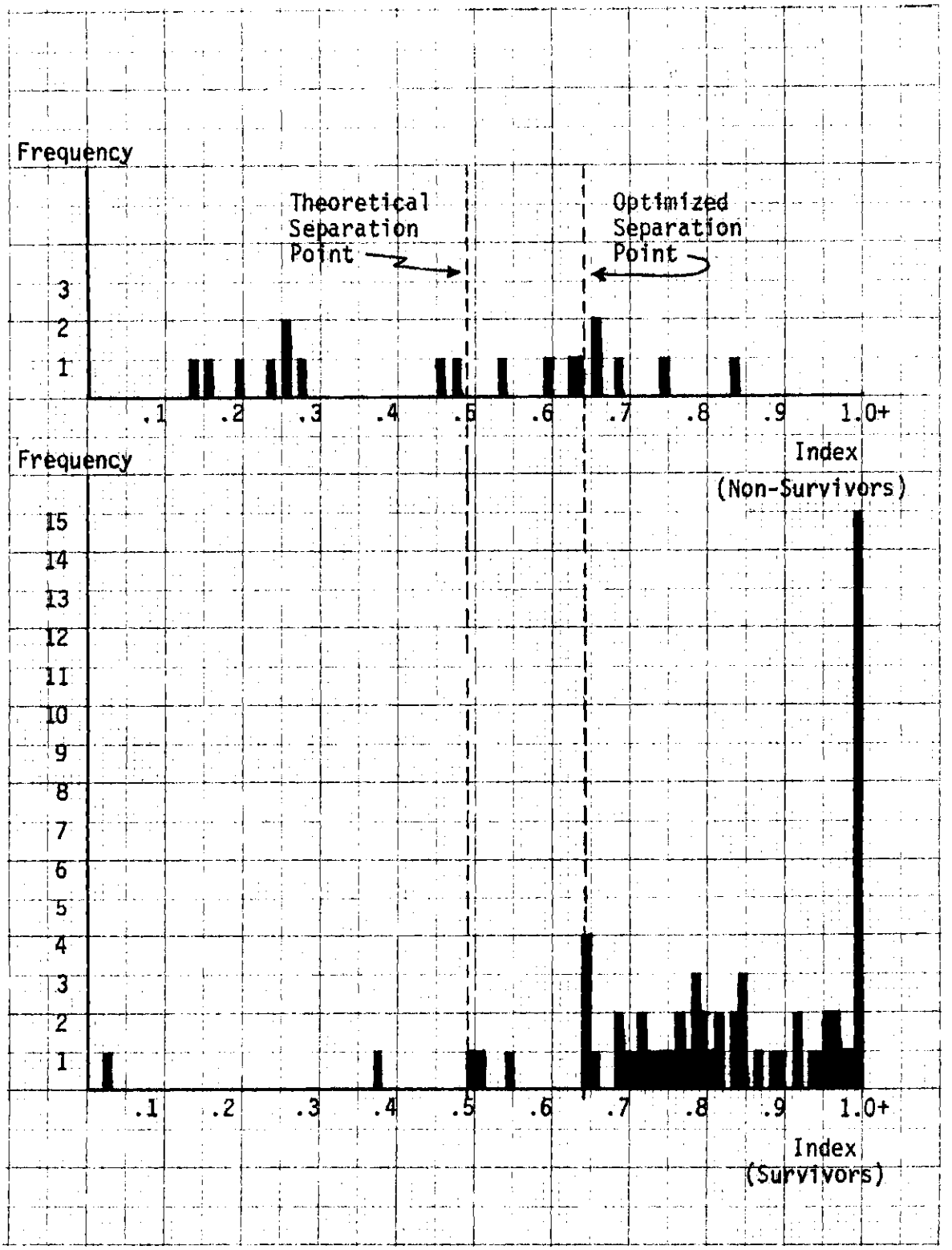

Figure 2. Misclassification Rates--Model B

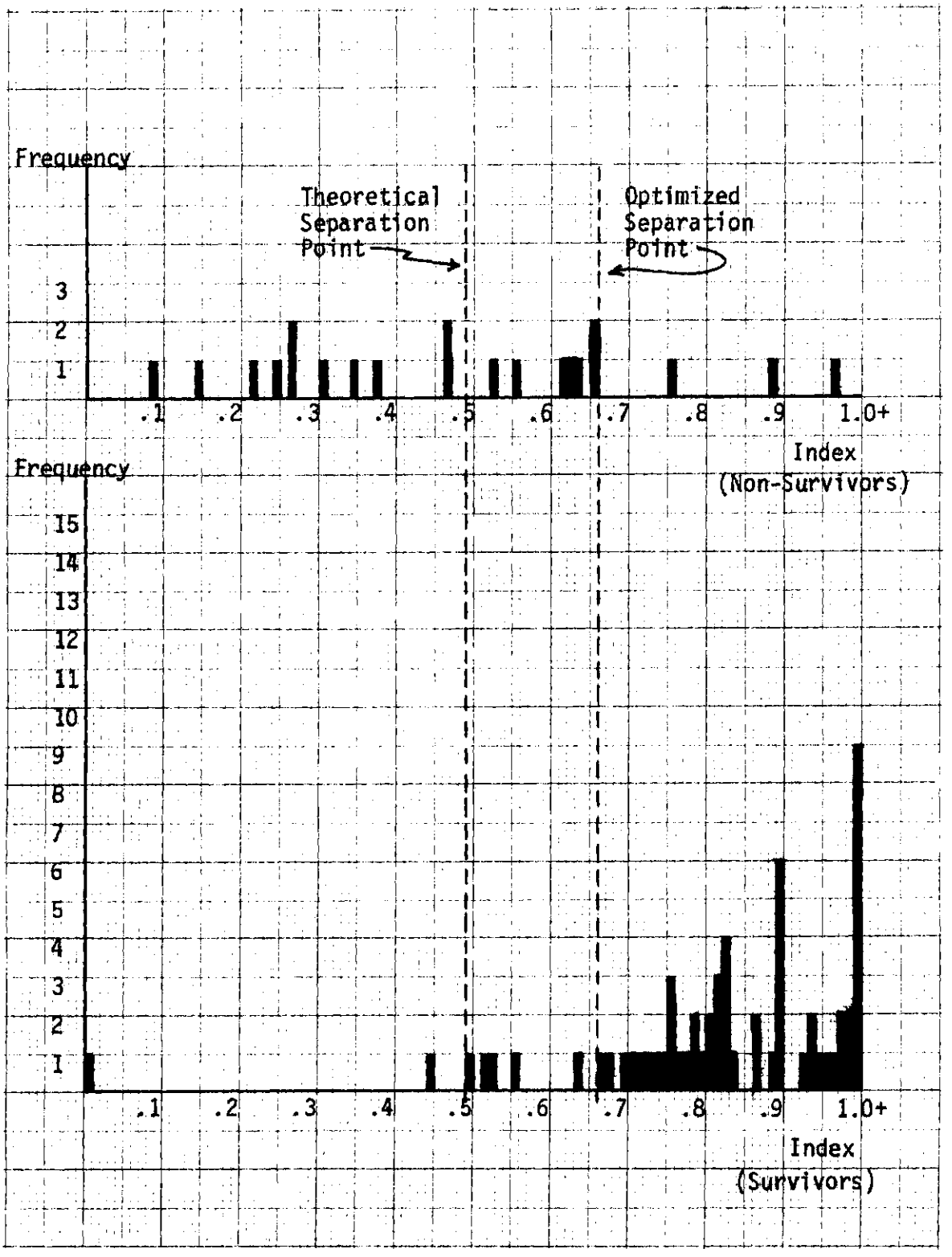

Figure 3. Misclassification Rates--Model C

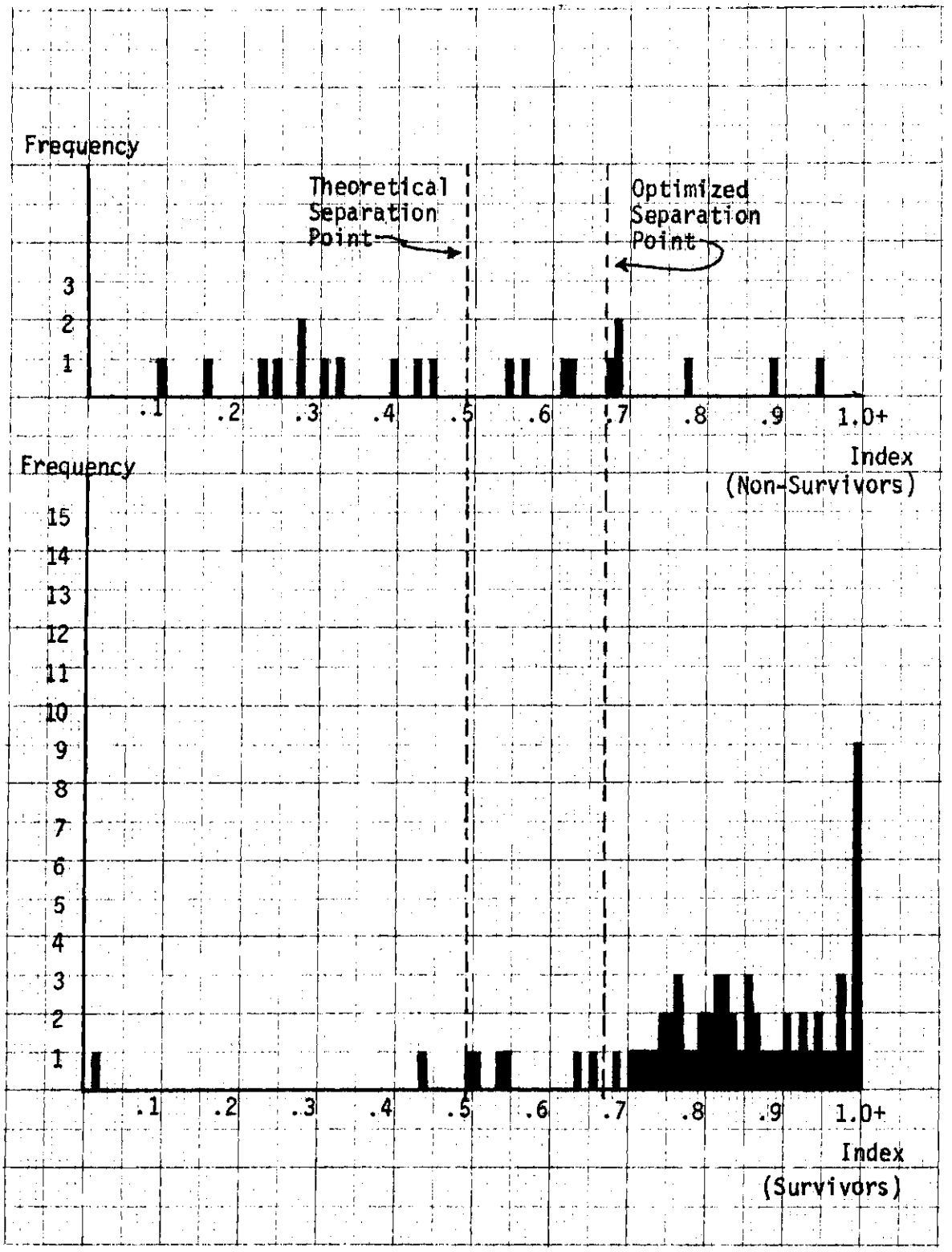

Figure 4. Misclassification Rates--Model D

among the four candidates. The "best" model was selected on the basis of the following criteria:

1. Maximization of the coefficient of multiple determination, R^2.
2. Minimization of the misclassification rates.
3. Minimization of statistical "lack of fit."

In addition, the residuals of the selected model should exhibit no predominant characteristics that would tend to violate the error assumptions (see p. 45).

With respect to the first criterion, Model B maximizes R^2. It should also be observed that the R^2 of Model A is very close to that of Model B, whereas the coefficients of the other two models are at distinctly lower levels. Examining the differences in the two sets of models (Table 5), it is evident that the higher R^2 statistic is attributable to the inclusion of the cross product, rather than Euclidean Distance, terms to represent interaction between the variables. This phenomena can possibly be explained by the fact that the Euclidean distance term supresses the values of potentially important individual variables.

As shown in Table 11 and Figures 1, 2, 3, and 4, Model B minimizes the theoretical misclassification rate; Models B and C minimize the optimized rate. In addition, all of the models tend to partition the cases into two groups, thereby allowing discrimination between survivors and non-survivors. Finally, referring to Tables 6, 7, 8, and 9, all

Table 11. Misclassification Rates

Misclassification Rate	Model			
	A	B	C	D
Theoretical	15.7%	13.3%	14.5%	14.5%
Optimized	13.3%	12%	12%	13.3%

regressions are statistically significant ($p < .014$).

Model B was selected as the "best" regression model. This model is significant at a level of $p = .014$, maximizes R^2, and minimizes the theoretical and optimized misclassification rates.

When examined further, it can also be shown that Model B can partition the group of patients into three groups with mortality ranging from less than 6 per cent to 90 per cent (see Table 12 and Figure 5). Operationally, this three-way classification would be more useful than the simple dichotomous survival classification as an index of initial condition.

Residual Analysis. From the plot of the residuals of Model B (Figure 6), the data do not appear to be normally distributed. However the residuals form a distribution that tends to be "bell-shaped" (as in a normal distribution), although definitely skewed to the right. Thus while the distribution does not appear to be strictly normal, it does possess normal characteristics (e.g., unimodal central tendency).

As noted by Bush (1973), the assumption of normality is rather robust[30] in multiple linear regression. Therefore one can conclude that the observed non-normality of the residuals will not invalidate the basic assumption of a linear model.

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[30]Unless the assumption is grossly violated, the statistical effects are very small.

Table 12. Mortality Associated with the Index of Initial Condition

Index Value	Mortality
0 - .32	90%
.33 - .66	50%
.67 - 1.00	5.5%

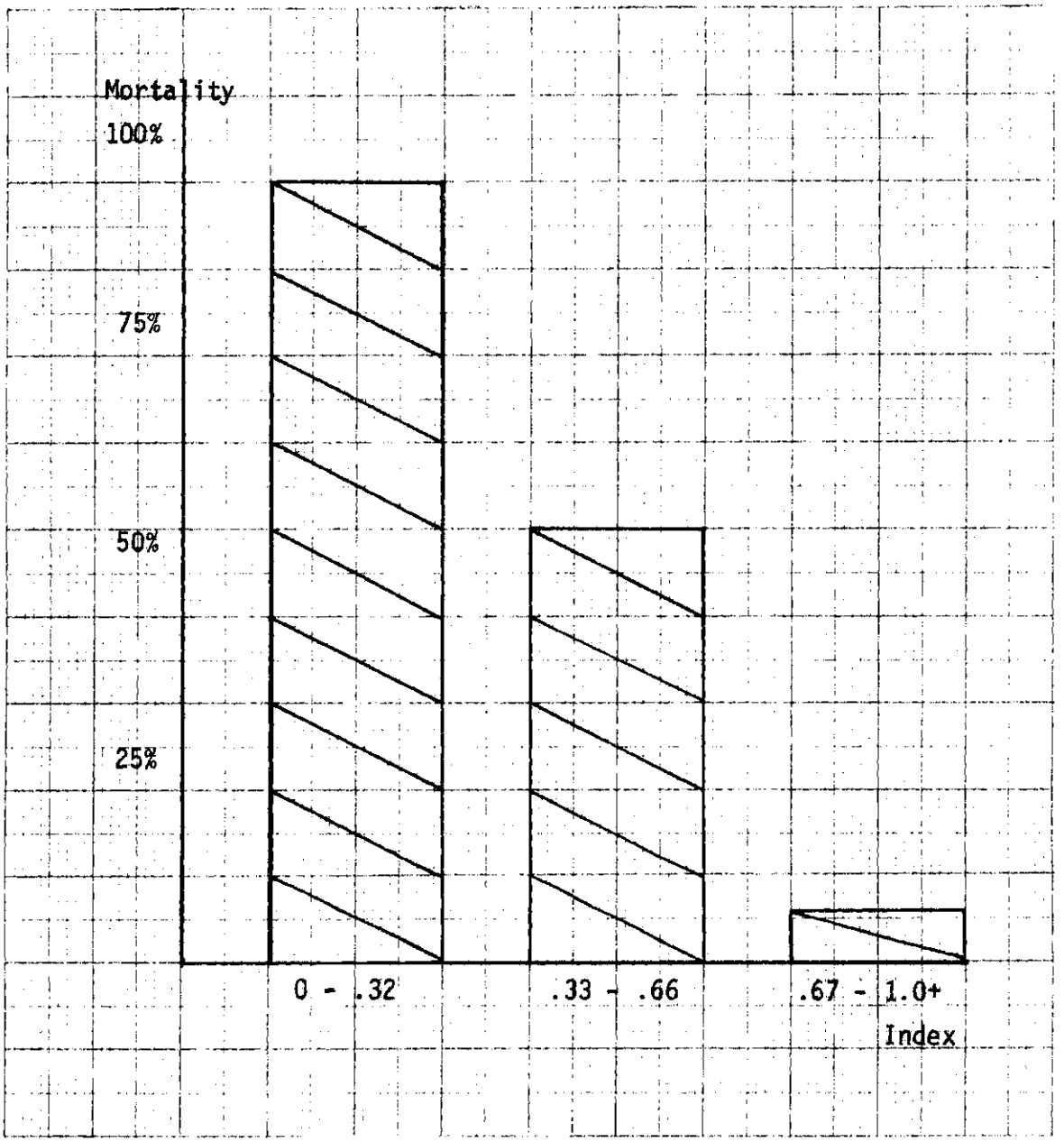

Figure 5. Mortality Associated with the Index

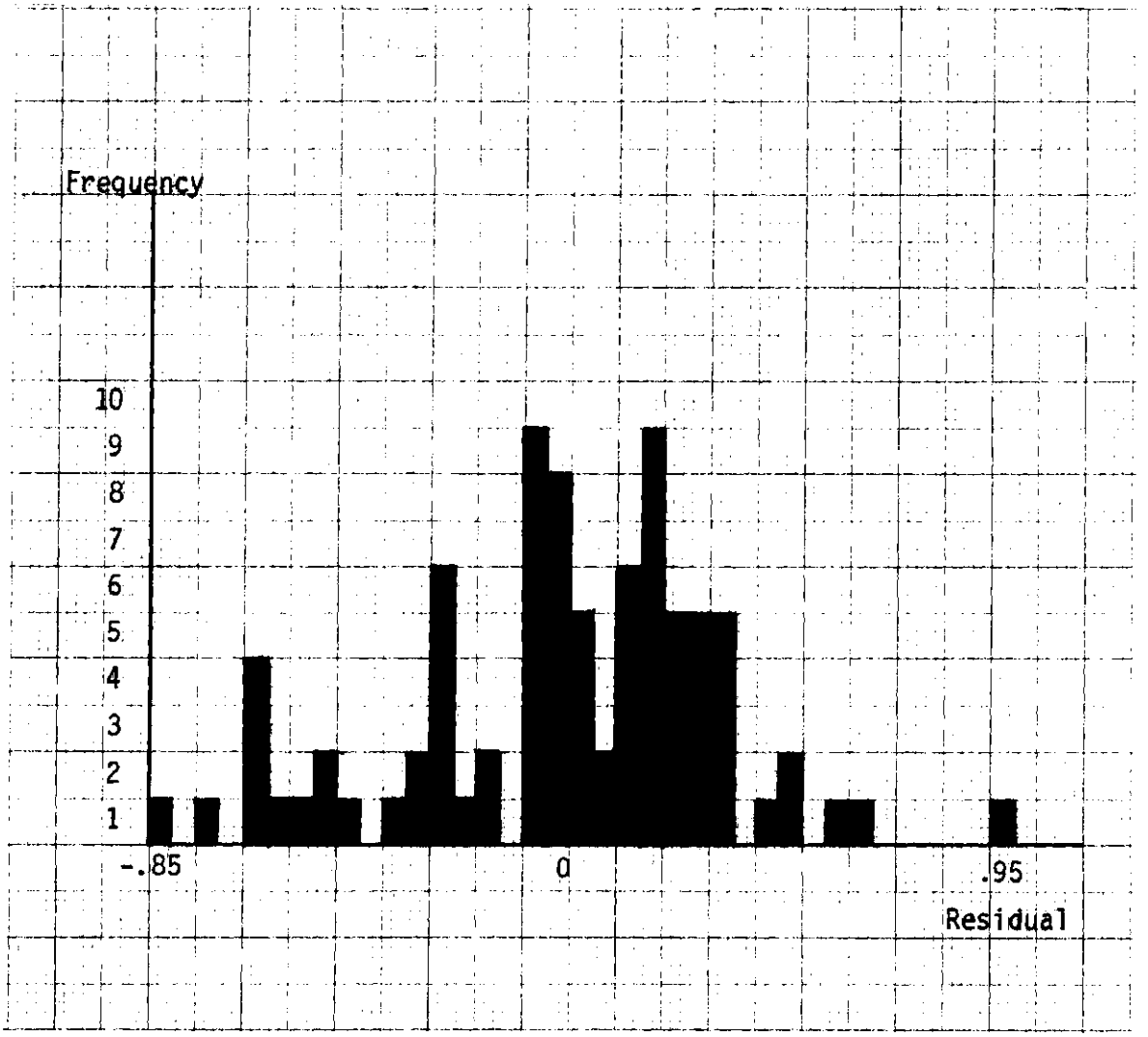

Figure 6. Residual Plot--Model B

Characteristics of the Population

The index of initial condition (Model B) was based on a total of 83 cases (10 cases were deleted due to missing data elements). Of these cases, the average age of the patients was 62 years, 94 per cent were white, and 74 per cent were male. Although the sample obviously is not composed of equal proportions of the various sub-groups (e.g., male vs. female), it is probably representative of the typical AMI patient.

T-tests between survivors and non-survivors indicated significant differences between the mean values of the initial measurements of the vital signs (see Table 13). These results are not surprising since the vital signs were known to be good predictors of survival [Peel et al. (1962), Hughes et al. (1963), Shubin et al. (1968), Norris et al. (1969), Verdouw et al. (1975)].

The Stabilization Outcome Measure

This section presents the results of the Delphi study of the dependent variable, level of stabilization, and the development of the linear regression model generalizing the relationship between the dependent variable and its predictors.

The Delphi Study

The Delphi experiment was conducted over two rounds in which two panels of physicians participated in parallel exercises designed to yield independent estimates of level of stabilization for a set of 20 patient cases. The following

Table 13. Characteristics of the Sample on Which the Index of Initial Condition was Based

Variable	Mean Value Survivors (N=69)	Mean Value Non-Survivors (N=24)	t-value	p
LOS[a]	17.65	6.0	5.66	.000[c]
AGE	61.4	64.8	-1.13	.263
SEX[b]	.27	.26	.05	.958
ASBP	139.6	83.7	3.37	.002[c]
ADBP	83.3	45.4	4.16	.000[c]
APULS	83.1	52.4	2.81	.009[c]
ARESP	19.6	12.4	2.86	.008[c]

[a]Length of stay

[b]Since males = 0 and females = 1 in the coding scheme employed herein (see p. 37), the 'sex' figures in this table can be interpreted as the proportion of females in the sample.

[c]Statistically significant, $p < .01$.

sections examine the degree to which each panel obtained consensus (intra-panel agreement) and the extent to which the panels agreed with each other (inter-panel agreement).

Intra-Panel Agreement. The results of round one are shown in Table 14. "Consensus" was obtained in Panel #1 for 14 cases; Panel #2 obtained consensus in 19 cases. As previously indicated, consensus was arbitrarily defined in terms of a truncated range (TR) of 50 points or less on the stabilization scale. The TR is computed by taking the difference between the highest and lowest response for a patient case, after elimination of the pair of initial highest and lowest responders.[31]

A closer examination of Table 14 reveals that 8 and 14 cases, in Panels #1 and 2 respectively, had TRs of 25 or less. On only one case (#23) was there absolute consensus. In that particular case, a rating of '-100' was obviously required since the patient's vital signs were at zero levels both at the scene and upon arrival of the emergency department.

In general, it would appear that at the end of round one, Panel #2 achieved a higher degree of consensus than did Panel #1, having obtained agreement in five more cases. In addition, the highest TR for Panel #2 is equal to 75 whereas

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[31]Delphi studies often use the interquartile range as a measure of consensus. However, it was felt that this measure would eliminate too large a portion of the already small panel sizes in the determination of consensus.

Table 14. Results of Round One of the Delphi Exercise

Case	Panel #1					Panel #2						R_1	R_2	TR_1	TR_2	Consensus #1	Consensus #2
	1-1	1-2	1-3	1-4	1-5	2-1	2-2	2-3	2-4	2-5	2-6						
6	- 50	- 25	- 50	+ 75	0	- 25	- 25	0	- 25	+ 25	0	125	50	50	25	a	b
13	0	+100	0	+ 75	+100	0	0	0	0	+ 75	0	100	75	100	0		c
15	- 75	- 75	- 75	- 75	- 50	- 50	- 75	- 50	- 50	- 50	- 50	25	25	0	0	c	c
19	0	+ 75	0	+ 75	+ 75	0	+ 25	0	- 50	+ 25	0	75	75	75	25		b
22	0	+ 75	0	+ 75	+ 75	0	0	0	0	+ 75	0	75	75	75	0		c
23	-100	-100	-100	-100	-100	-100	-100	-100	-100	-100	-100	0	0	0	0	d	d
29	+ 50	+ 50	+ 75	+ 75	+ 25	+ 25	+ 75	+ 50	0	+ 75	0	50	75	25	75	b	
31	- 50	- 25	- 25	+ 75	+ 50	0	- 25	0	0	+ 75	0	125	100	75	0		c
32	- 25	+ 25	0	+ 50	+ 25	+ 25	- 50	+ 50	0	+ 50	0	75	100	25	50	b	a
34	- 25	- 25	- 25	+ 75	+ 75	0	0	0	0	+ 75	0	100	75	100	0		c
43	0	+100	0	+ 75	+100	0	+ 25	0	0	+ 75	0	100	75	100	25		b
51	- 50	0	0	+ 50	+ 25	+ 25	0	+ 50	0	+ 25	+ 25	100	50	25	25	b	b
58	+ 25	+ 75	0	+ 75	+100	0	+ 25	0	0	+ 75	0	100	75	50	25	a	b
61	- 25	0	+ 25	+ 75	+ 75	+ 25	- 25	+ 25	0	+ 50	0	100	75	50	25	b	a
62	+ 50	+ 25	+ 50	+ 25	+ 50	+ 25	+ 75	+ 25	- 75	0	+ 50	25	150	25	50	b	a
68	- 75	0	NR	- 75	- 25	- 25	0	- 50	- 50	- 25	- 25	75	50	50	25	a	b
70	+ 25	+ 50	0	+ 75	+ 75	+ 25	+ 50	0	0	+ 75	0	75	75	50	50	a	a
77	- 25	+ 25	- 50	+ 50	+ 25	0	+ 50	+ 50	0	+ 25	0	100	50	50	50	a	a
87	+ 25	0	+ 25	+ 75	+ 25	+ 25	+ 75	+ 25	0	+ 25	0	75	75	0	25	c	b
89	+ 75	+ 25	+ 75	+ 50	+ 75	+ 75	+ 75	+ 25	+ 25	+ 25	+ 75	50	50	25	50	b	a

[a]Consensus obtained ($25 < TR \leq 50$)
[b]Consensus obtained ($0 < TR \leq 25$)
[c]Consensus obtained ($TR = 0$)
[d]Consensus obtained ($R = 0$)
NR = no response

Panel #1 had several TRs equal to 100.

Referring to the ranges of the scores, both panels widely disagreed (range > 100) on a number of cases. In fact, if the range rather than the TR had been used to indicate consensus, Panel #1 would have achieved consensus on only five cases, and Panel #2 would have achieved consensus on only six cases.

The results of round two are presented in Table 15. In this round, the high and low responses, together with representative comments were "fed-back" to the participants. It was anticipated that a greater degree of consensus would be obtained. It should be noted that all of the cases, with the exception of case #23, on which unanimous agreement was obtained, were reconsidered on the second round, regardless of the degree of consensus achieved in the first round. The rationale for this approach was to attempt to obtain the highest possible degree of consensus for each case. In addition, since the definition of stabilization was clarified for consideration in round two, it was thought desirable to allow the panels to reconsider all of the cases in light of the new information.

As shown in Table 15, consensus (TR $\leq$ 50) was obtained in 19 cases for both panels. TRs of 25 or less were obtained in 17 cases for Panel #1 and in 14 cases for Panel #2. TRs of zero (0) were obtained in eight cases for both panels. Unanimous agreement was achieved in one and four cases for

Table 15. Results of Round Two of the Delphi Exercise

Case	Panel #1					Panel #2						R_1	R_2	TR_1	TR_2	TA_1	TA_2	Consensus	
	1-1	1-2	1-3	1-4	1-5	2-1	2-2	2-3	2-4	2-5	2-6							#1	#2
6	+ 50	0	- 50	0	- 50	0	0	0	NR	0	0	100	0	50	0	-17	0	a	d
13	+100	+ 75	+ 75	+ 75	+ 75	0	+ 25	+ 50	- 25	+ 50	+ 25	25	75	0	50	+75	+25	c	a
15	- 75	- 75	- 75	- 50	- 75	- 75	- 75	- 50	- 75	- 75	- 50	25	25	0	25	-75	-69	c	b
19	+100	+ 75	+ 75	+100	+ 50	0	0	0	- 50	+ 25	0	50	50	25	0	+83	0	b	c
22	+ 75	+ 50	+ 75	+ 75	+ 50	0	+ 25	+ 25	+ 25	+ 75	0	25	75	25	25	+67	+19	b	b
23	-100	-100	-100	-100	-100	-100	-100	-100	-100	-100	-100	0	0	0	0	-100	-100	d	d
29	+ 75	+ 50	+ 50	+ 75	+ 75	+ 25	+ 50	+ 50	0	+ 75	0	25	75	25	50	+67	+31	b	a
31	+ 50	+ 25	- 50	- 25	- 25	0	0	+ 50	0	+ 25	0	100	50	50	25	- 8	+ 6	a	b
32	+ 50	+ 25	0	+ 25	- 25	+ 25	- 25	+ 25	0	0	- 50	75	75	25	50	+17	0	b	a
34	+ 75	+ 50	- 25	+ 25	- 25	NR	+ 25	+ 50	+ 25	+ 25	0	100	50	75	0	+17	+25		c
43	+100	+ 75	+ 75	+100	+ 75	NR	+ 25	+ 50	0	+ 75	0	25	75	25	50	+83	+25	b	a
51	- 25	+ 25	- 25	0	- 25	+ 25	+ 25	0	+ 25	0	+ 25	50	25	25	25	-17	+19	b	b
58	+100	+ 75	+ 50	+ 75	+ 75	+ 25	+ 25	+ 25	0	+ 50	0	50	50	0	25	+75	+19	c	b
61	+ 75	+ 50	0	+ 50	+ 25	+ 25	+ 25	+ 50	- 25	+ 25	+ 25	75	75	25	0	+42	+25	b	c
62	+ 25	+ 25	+ 25	+ 25	+ 50	- 25	+ 25	0	- 50	- 50	+ 50	25	100	0	75	+25	-13	c	
68	- 50	- 50	- 50	- 25	- 50	- 25	- 25	- 25	- 25	- 25	- 50	25	25	0	0	-50	-25	c	c
70	+ 75	+ 50	+ 25	+ 50	+ 50	+ 25	+ 25	+ 50	+ 25	+ 50	0	50	50	0	25	+50	+31	c	b
77	- 25	0	- 50	- 25	- 50	+ 25	+ 25	+ 25	+ 25	+ 25	+ 25	50	0	25	0	-33	+25	b	d
87	+ 75	+ 25	0	+ 25	+ 50	+ 25	+ 25	+ 25	+ 25	+ 25	+ 25	75	0	25	0	+33	+25	b	d
89	+ 75	+ 25	+ 50	+ 50	+ 50	+ 50	+ 50	0	0	+ 25	+ 50	50	50	0	50	+50	+31	c	a

[a]Consensus obtained ($25 < TR \leq 50$)
[b]Consensus obtained ($0 < TR \leq 25$)
[c]Consensus obtained ($TR = 0$)
[d]Consensus obtained ($R = 0$)
NR = no response

Panels #1 and #2 respectively. In only one case (for each panel) was consensus not achieved.

Again referring to the ranges of the scores, no wide disagreement (as previously defined as a range > 100) appears to exist. Moreover, if consensus was defined as a range of 50 or less, Panel #1 would have achieved consensus on 14 cases and Panel #2 would have achieved consensus on 13 cases.

In addition to examining the degree of consensus obtained, it is also useful to examine the extent to which consensus can be attributed to the Delphi process. This concept becomes especially important in determining if consensus was obtained by chance or if true agreement (within the panels) exists. In this regard, Tables 16 and 17 present the changes in TRs (ΔTR) for each of the 20 patient cases as considered by Panels #1 and #2 respectively. A negative change in TR indicates convergence and a positive change indicates divergence. Hence, convergence was demonstrated in 13 cases (65%) by Panel #1 and in 8 cases (40%) by Panel #2. Conversely, divergence was demonstrated in only one case (5%) by Panel #1 and in six cases (30%) by Panel #2.

In summary, one can conclude that both panels achieved a reasonable degree of consensus as indicated by both the TRs and ranges of the scores. However, it appears that Panel #1 achieved a slightly higher degree of consensus. Moreover, one might have more confidence in the results obtained from Panel #1 since the ratio of convergence to divergence of the

Table 16. Changes in Truncated Ranges--Panel #1

Case	TR_1	TR_2	ΔTR (TR_2-TR_1)
6	50	50	0
13	100	0	-100
15	0	0	0
19	75	25	- 50
22	75	25	- 50
23	0	0	0
29	25	25	0
31	75	50	- 25
32	25	25	0
34	100	75	- 25
43	100	25	- 75
51	25	25	0
58	50	0	- 50
61	50	25	- 25
62	25	0	- 25
68	50	0	- 50
70	50	0	- 50
77	50	25	- 25
87	0	25	25
89	25	0	- 25

Note: $\Delta TR < 0$, convergence (13/20 = 65%)
$\Delta TR > 0$, divergence (1/20 = 5%)
$\Delta TR = 0$, no change (6/20 = 30%)

Table 17. Changes in Truncated Ranges--Panel #2

Case	TR_1	TR_2	ΔTR (TR_2-TR_1)
6	25	0	-25
13	0	50	+50
15	0	25	+25
19	25	0	-25
22	0	25	+25
23	0	--	0
29	75	50	-25
31	0	25	+25
32	50	50	0
34	0	0	0
43	25	50	+25
51	25	25	0
58	25	25	0
61	25	0	-25
62	50	75	+25
68	25	0	-25
70	50	25	-25
77	50	0	-50
87	25	0	-25
89	50	50	0

Note: $\Delta TR < 0$, convergence (8/20 = 40%)
$\Delta TR > 0$, divergence (6/20 = 30%)
$\Delta TR = 0$, no change (6/20 = 30%)

20 cases is 13:1 indicating a strong tendency toward true agreement within the panel, as compared to a ratio of 8:6 for Panel #2, a somewhat tenuous figure.

In addition to obtaining a higher degree of consensus and demonstrating more convergence, Panel #1 experts appeared to be slightly more confident in their estimates of stabilization, as shown in Table 18. Furthermore, the Panel #1 experts expressed slightly greater satisfaction with the concept of stabilization although neither panel was highly satisfied (see Table 19).

Inter-Panel Agreement. Another measure of the validity of the stabilization experiment is the extent to which the two independent panels arrive at the same conclusions given the same judgmental problem (i.e., the assessment of level of stabilization for the group of 20 patient cases). If inter-panel agreement is high, one can more justifiably argue that the results obtained in this Delphi study are valid (Note that such agreement does not prove the validity of the study, but is suggestive of validity). However, if the two panels significantly disagree, the interpretation becomes even less clear. Actually several interpretations could be made:

1. One panel is "correct," the other incorrect.
2. Both panels are "wrong."
3. The judgmental problem is so "fuzzy" and ill-defined that it is difficult,

Table 18. Panel Confidence in the Stabilization Estimates

Panel	No Confidence	Little Confidence	Some Confidence	Much Confidence	Full Confidence
#1[a]			3		2
#2[b]		1	4	1	

[a]Consisting of five experts.

[b]Consisting of six experts.

Table 19. Panel Satisfaction with the Concept of Stabilization

Panel	Extremely Dissatisfied	Slightly Dissatisfied	Adequately Satisfied	Very Satisfied	Extremely Satisfied
#1		2	2	1	
#2	2	2	2		

if not impossible, for either of the panels to make valid judgments.

A paired t-test between the mean stabilization scores[32] of the two panels indicated no significant difference (see Table 20). However, the small sample size (n=20) coupled with the high standard deviation of the responses may mask some true differences. For example, the two panels disagreed by over 80 points on case #19 (see Table 15).

Further insight into inter-panel agreement can be obtained by examining the extent to which the panels agree on the gross classification of a patient as either stable [positive (+) or zero TA] or unstable [negative (-) rating]. As shown in Table 21, the panels agree with respect to 15 out of the 20 cases (75%).

The above tests for inter-panel agreement indicate that a reasonable amount of agreement was obtained. However, it appears that the concept of stabilization (as defined herein) is somewhat fuzzy as indicated by the 25% of the cases on which the panels disagreed.

A closer examination of the five cases on which the panels disagreed (see Table 22) shows that all of the responses fall within the center part of the stabilization outcome scale, the highest range being from -33 to +25.

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[32]Final mean scores for each case as generated by each panel are represented in terms of a "truncated average" (TA). The TA is defined as the mean of the responses contained within the TR. These values are shown in Table 15.

Table 20. Paired t-test Between Panel #1 and Panel #2 Responses

Variable	Code	Mean	Standard Deviation	Mean Difference	Standard Deviation	t-value	p
TA-Panel #1	STAB1	19.2	54.1	11.80	9.4	1.25	.227[a]
TA-Panel #2	STAB2	7.5	37.8				

[a]Statistically not significant, $p > .05$.

Table 21. Inter-Panel Agreement on the Stable/Unstable Classification

Case	Panel #1	Panel #2	Agreement
6	-	0[a]	No
13	+	+	Yes
15	-	-	Yes
19	+	0	Yes
22	+	+	Yes
23	-	-	Yes
29	+	+	Yes
31	-	+	No
32	+	0	Yes
34	+	+	Yes
43	+	+	Yes
51	-	+	No
58	+	+	Yes
61	+	+	Yes
62	+	-	No
68	-	-	Yes
70	+	+	Yes
77	-	+	No
87	+	+	Yes
89	+	+	Yes

[a]By definition, zero (0) is a stable classification.

Table 22. Panel Disagreement--Stable Versus Unstable

Case Number	Panel #1 Classification	Panel #2 Classification
6	-17	0
31	- 8	+ 6
51	-17	+19
62	+25	-13
67	-33	+25

These results are not surprising since the scale is "fuzzy" at the zero (0) point. Hence, some disagreement is expected in "borderline" classifications of stable versus unstable. Thus one can conclude that the two panels agree with respect to the dichotomous stable/unstable classification.

The Regression Models

Six alternative regression models were formulated to represent stabilization based on the results of the Delphi study. To begin, separate models were developed using both the responses from Panels #1 (STAB1) and #2 (STAB2), as the dependent variables.

In addition, alternative representations of vital signs were considered. These included Euclidean distances, changes in squared vital signs (e.g., $ESBP1^2 - ASBP^2$) and changes in vital signs (e.g. ESBP1 - ASBP). The number of variables considered in any one model was necessarily limited due to the small sample size (20). Hence, combinations of no more than six (6) variables were considered as candidate regression models. Given this restriction, it was not possible to study the effects of all the variables included in the basic data set (see Table 2), particularly single vital sign measurements (e.g. ASBP, ESBP1, ADBP, EDBP1...) and interactions between the vital signs (e.g. ASBP x APULS, ESBP1 x EPULS1), with the exception of the Euclidean distance terms. Accordingly, six alternative models were developed and are hereinafter referred to as Models I, II, III, IV, V,

and VI, respectively.

The variables initially included in each model are listed in Table 23. The variables entered and removed from the equations as a result of the stepwise selection procedure are listed in Tables 24 through 29. Also presented in Tables 24 through 29 are the significance of regression, the coefficient of multiple determination (R^2) and the coefficient of multiple correlation (R). Table 30 presents the corresponding regression equations.

Internal Validity. The internal statistical properties of the regression models (R^2, significance of regression, residuals) were assessed in order to (1) determine if the models adequately represent the physicians' process of classification by stabilization level and (2) select the best model from among the six alternative models.

As shown in Table 31, Model I maximizes R^2 (=.87) and is highly significant (p=0). Model II has the next largest R^2 (=.84). All other models have R^2 statistics at appreciably lower levels and are not statistically significant. It should be noted that both Models I and II included Euclidean distance terms rather than changes in vital signs or changes in squared vital signs. Equally significant is the observation that given identical sets of independent variables, the models based on STAB1 (assessment of level of stabilization by Panel #1) as the dependent variable have consistently higher R^2 statistics than do the models based on STAB2 (assessment of

Table 23. Variables Initially Included in the Stabilization Models

Variable	Symbol (if different)	Regression Model					
		I	II	III	IV	V	VI
AGE		X	X	X	X	X	X
SEX		X	X	X	X	X	X
AEUCLID		X	X				
EEUCLID1		X	X				
(ESBP1-ASBP)	XSBP			X	X		
(EDBP1-ADBP)	XDBP			X	X		
(EPULS1-APULS)	XPULS			X	X		
(ERESP1-ARESP)	XRESP			X	X		
($ESBP1^2$-$ASBP^2$)	XXSBPSQ					X	X
($EDBP1^2$-$ADBP^2$)	XXDBPSQ					X	X
($EPULS1^2$-$APULS^2$)	XXPULSQ					X	X
($ERESP1^2$-$ARESP^2$)	XXRESPQ					X	X

Table 24. The Stabilization Outcome Measure--Model I

Step	Variable Entered Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	EEUCLID1	69.80754	.000	.89163	.79501	69.80754	.000
2	SEX	5.15003	.037	.91797	.84267	45.52611	.000
3	AGE	2.14781	.162	.92806	.86129	33.11590	.000
4	AEUCLID	1.43345	.250	.93455	.87339	25.86814	.000

Table 25. The Stabilization Outcome Measure--Model II

Step	Variable Entered Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	EEUCLID1	42.99661	.000	.83958	.70490	42.99661	.000
2	SEX	8.07179	.011	.89438	.79991	33.98039	.000
3	AEUCLID	1.75687	.204	.90538	.81970	24.24779	.000
4	AGE	2.05478	.172	.91729	.84143	19.89841	.000

Table 26. The Stabilization Outcome Measure--Model III

Step	Variable Entered Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	AGE	4.51417	.048	.44778	.20050	4.51417	.048
2	XPULS	2.84375	.110	.56132	.31508	3.91016	.040
3	XSBP	1.34838	.263	.60689	.36831	3.10965	.056
4	XRESP	.56118	.465	.62537	.39109	2.40857	.095
5	SEX	.11613	.738	.62937	.39610	1.83654	.170
6	XDBP	.09077	.768	.63268	.40029	1.44619	.270

Table 27. The Stabilization Outcome Measure--Model IV

Step	Variable Entered Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	XPULS	1.81422	.195	.30259	.09156	1.81422	.195
2	XSBP	3.19514	.092	.48507	.23529	2.61531	.102
3	AGE	.84172	.373	.52298	.27351	2.00788	.153
4	XDBP	.11788	.736	.52837	.27917	1.45235	.266

Table 28. The Stabilization Outcome Measure--Model V

Step	Variable Entered Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	XXRESPQ	5.22825	.035	.47443	.22508	5.22825	.035
2	AGE	2.71167	.118	.57592	.33168	4.21854	.033
3	XXPULSQ	1.18559	.292	.61465	.37779	3.23826	.050
4	XXDBPSQ	.32395	.578	.62525	.39094	2.40706	.095
5	SEX	.19549	.665	.63193	.39933	1.86147	.165

Table 29. The Stabilization Outcome Measure--Model VI

Step	Variable Entered Removed	F to Enter or Remove	Significance	Multiple R	R Square	Overall F	Significance
1	XXPULSQ	5.49608	.031	.48365	.23391	5.49608	.031
2	AGE	1.34476	.262	.53858	.29007	3.47306	.054
3	XXSBPSQ	.26757	.612	.54932	.30175	2.30481	.116
4	XXDBPSQ	.25150	.623	.55970	.31326	1.71061	.200
5	SEX	.17850	.679	.56737	.32191	1.32924	.308
6	XXRESPQ	.01638	.900	.56812	.32276	1.03261	.448

Table 30. Alternative Regression Equations Representing the Stabilization Outcome Measure

Regression Model	Regression Equation
I	STAB1 = 136.98326-.72571729(AGE)+34.388212(SEX) -3.2373003(AEUCLID)-18.607334(EEUCLID1)
II	STAB2 = 19.380585+.43174774(AGE)+28.174941(SEX) +3.1706714(AEUCLID)-16.846809(EEUCLID)
III	STAB1 = 126.24485-1.5870284(AGE)-22.020085(SEX) +.23396596(XSBP)+.28405698(XDBP) -.57938619(XPULS)-1.1374417(XRESP)
IV	STAB2 = 39.978333-.52050252(AGE)+.32174632(XSBP) -.15731063(XDBP)-.57198396(XPULS)
V	STAB1 = 118.85791-1.4679669(AGE)-19.804142(SEX) +0.0024336214(XXDBPSQ)-0.0020263426(XXPULSQ) -0.028945781(XXRESPQ)
VI	STAB2 = 38.791476-.53224936(AGE)+12.826651(SEX) +0.00054690538(XXSBPSQ)-0.0015022363(XXDBPSQ) -0.0035432432(XXPULSQ)-0.0028826848(XXRESPQ)

Table 31. Comparison of the Regression Models

Model	Dependent Variable	Independent Variables (Initial Set)	R^2
I	STAB1	AGE, SEX, AEUCLID, EEUCLID1	.87[a]
II	STAB2	AGE, SEX, AEUCLID, EEUCLID1	.84[a]
III	STAB1	AGE, SEX, XSBP, XDBP, XPULS, XRESP	.40
IV	STAB2	AGE, SEX, XSBP, XDBP, XPULS, XRESP	.28
V	STAB1	AGE, SEX, XXSBPSQ, XXDBPSQ, XXPULSQ, XXRESPQ	.40
VI	STAB2	AGE, SEX, XXSBPSQ, XXDBPSQ, XXPULSQ, XXRESPQ	.32

[a]Statistically significant, $p < 0.001$.

stabilization by Panel #2). Accordingly, Model I can be considered as the "best" overall model. With respect to the STAB2 models, Model II was selected. Both models have high R^2 and are both highly significant.

The residuals of Models I and II are plotted in Figures 7 and 8, respectively. Neither plot appears to be strictly normally distributed, although both possess some normal characteristics (e.g., unimodal central tendency). It is difficult to interpret the plots due to the small sample size, but due to the robustness of the assumption of normality, one can probably conclude that the observed non-normality will not invalidate the model.

Characteristics of the Sample

The stabilization model was based on a sample of 20 patient cases. The 20 cases represent a random sample of the total 83 case data base. The sample was stratified with regard to survivors and non-survivors in the same proportion (75%/25%) as contained in the overall sample. The number of cases was not statistically selected but rather were considered to be reasonable for the panel to consider.

The characteristics of the patients in the 20 case sample closely resemble those in the 83 case sample. The average age of the patients in the 20 case sample was 62 years, 95 per cent were white, and 85 per cent were male, as compared to overall sample parameters of 62 years, 94 per cent white, and 74 per cent male. T-tests between the two samples indicated no significant differences.

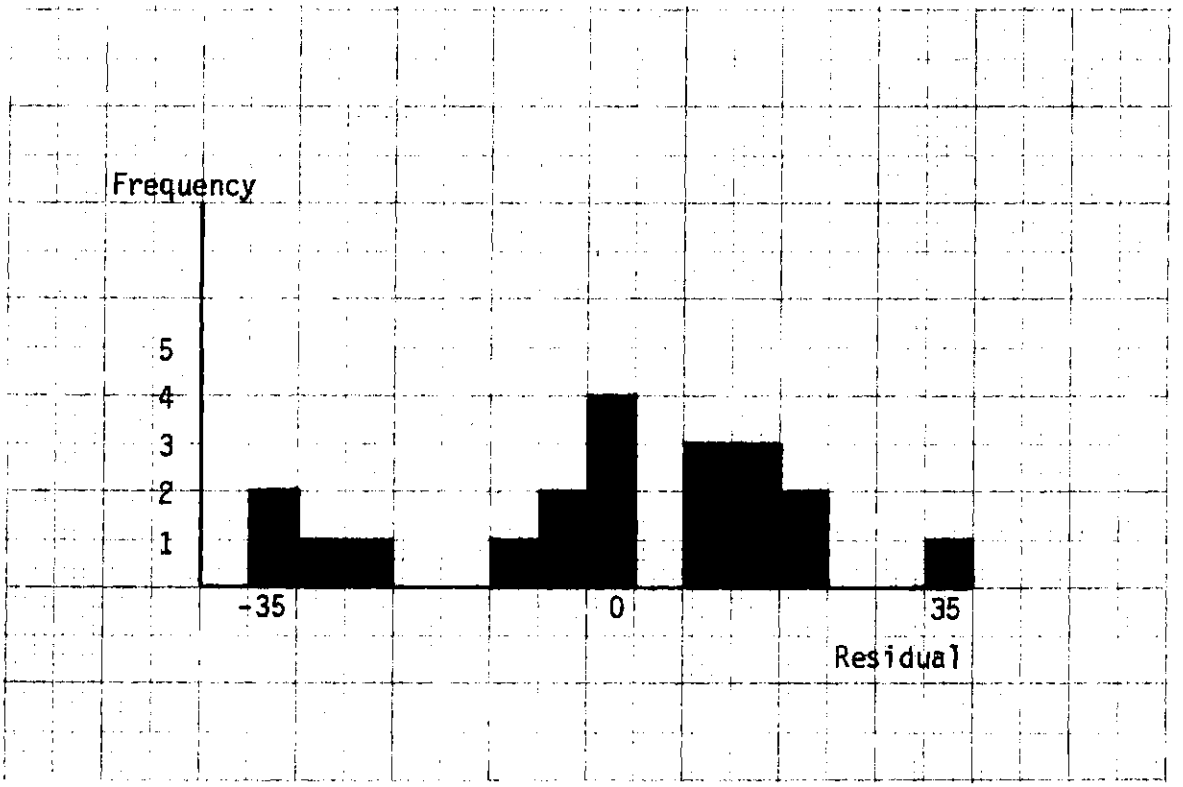


Figure 7. Residual Plot--Model I

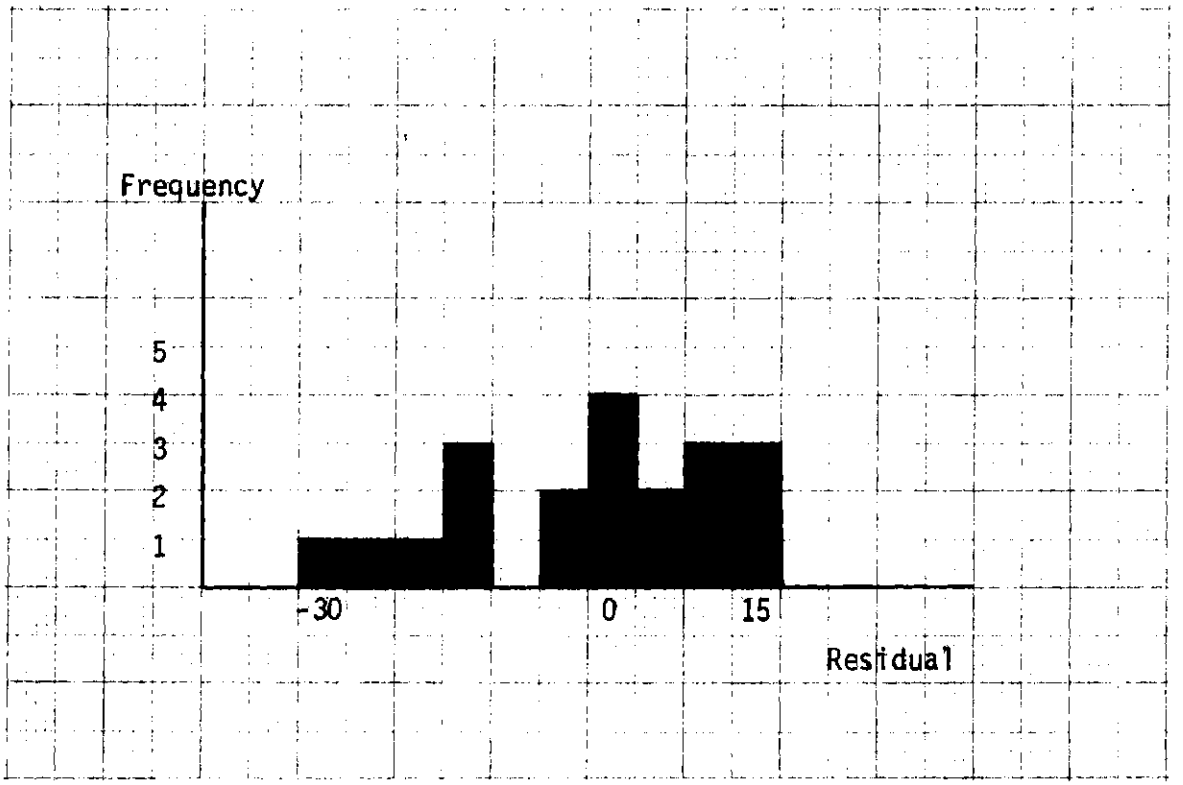


Figure 8. Residual Plot--Model II

CHAPTER VII

DISCUSSION OF RESULTS

The following chapter provides additional interpretation of the results of the thesis.

The Index of Initial Condition

The regression model chosen to represent the index of initial condition (Model B) had an R^2 of approximately 0.4 indicating that 40% of the variance had been explained by the model. While not indicative of a high degree of correlation (R=.63), it would seem to be a reasonable amount of variance to be explained by severity of illness alone. Ostensibly, medical intervention would explain much of the residual variance.

With respect to predictive accuracy, the optimized and theoretical misclassification rates of 12% and 13.3% respectively, compare favorably with the misclassification rates yielded in similar studies. In this regard, Table 32 presents the misclassification rates obtained with the coronary prognostic indices of Hughes et al., Shubin et al., and Verdouw et al. as compared to those obtained in the present study. The rates derived for the CPIs range from 7% to over 10%. The small difference between these rates and those obtained herein is not particularly significant and is

Table 32. Misclassification Rates--Coronary Prognostic Indices Versus the Index of Initial Condition (Model B)

CPI	Misclassification Rate(s)
Hughes et al. (1963)	8.3%[a]
Shubin et al. (1968)	7%[b]
Verdouw et al. (1975)	9%,10.7%[b]
The Index of Initial Condition (Model B)	12%[a],13.3%[b]

[a]Optimized misclassification rate.

[b]Theoretical misclassification rate.

probably attributable to the fact that the CPIs are based on information recorded at points in time closer to the target event (survival).

Application of the Model

Based on the results presented in Chapter VI, one can conclude that the index of initial condition is a reasonably valid predictor of mortality associated with AMIs. As such, it is a potentially useful instrument for controlling the effects of severity of infarction in research designs. In a statistical sense, the index can be considered as a blocking mechanism. For example, consider the evaluation of the use of xylocaine (a cardiac drug) to prevent ventricular fibrillation (extremely rapid, uncoordinated vibrations of the ventricles of the heart resulting in ineffective pumping action). Accordingly, one might be interested in the effect of the use of this drug on outcome (e.g., survival or stabilization).

Assume that data were collected on those patients who received the drug and those who did not. Further assume that, for the purposes of evaluation, the training and abilities of the emergency medical technicians, the ambulances and equipment, and the type of treatment available (with the exception of xylocaine) are statistically equivalent for each patient case. This assumption is not altogether untenable since the preceding factors are all controllable to a large degree.

However, the effects of patient condition cannot be

assumed to be equal. In fact, as Gibson (1974, p. 108) has observed, patients may live or die "solely as a function of their condition and that the only effect of EMS expenditures is influencing when and where death takes place." Thus, in order to evaluate the effects of the introduction of the drug, patient condition (or severity) must be accounted for. Statistically, this can be accomplished by segregating the patients according to the value of the index of initial condition, which has been shown to be related to mortality. Given this framework, a fixed effects analysis of variance design with complete blocks can be used to assess both the effects of intervention and patient condition on outcome.

The Stabilization Outcome Measure

The regression model chosen to represent level of stabilization (Model II) had an R^2 of 0.87 (R=0.93), indicating a very strong statistical relationship between stabilization and its predictors. Thus, the choice of a linear model appears to have been appropriate. In addition, it would appear that the panels assessed the patient cases in a consistent manner.

Although both intra-panel and inter-panel agreement were demonstrated, panel satisfaction was not as high as would have been desirable. At least some of the dissatisfaction can be attributed to the constraint that the measure be based on commonly available data included in both the

ambulance run report and the emergency department report. In this regard, the panels were asked to comment on the study as part of the second round of the Delphi exercise. Among the comments included:

> The basis of this study lacks an appreciation for the rhythm disturbance patterns necessary to establish degree of stability. Notation of normal sinus rhythm versus arrhythmias is important.
>
> Vital signs alone are not good indicators of stability for AMI.
>
> I just don't know how valuable this sort of assessment will prove to be. After all, the concept of pre-hospital coronary care (to me) is the the expedient treatment of warning arrhythmias to prevent lethal arrhythmias--or to take definitive action for such arrhythmias and information on arrhythmias was not considered.

These responses were anticipated by the investigator and indeed have much merit. In fact, most prospective studies of the pre-hospital clinical course of AMI center about the effects of life-threatening arrhythmias, due to their pronounced effect on mortality and the potential for taking definitive pre-hospital action. However, pre- and post-intervention arrhythmia data was not routinely available from existing records and thus could not be included in the study.

In addition, various panel members suggested that a number of other variables be included in the model. These include level of consciousness, type of treatment given by the emergency medical technician (EMT), regularity of the pulse, history of hypertension, shortness of breath, anxiety level, presence and type of pain, juglar vein distension,

skin color, and assessment of patient condition by the EMT. These comments were not unexpected since physicians are accustomed to making decisions based on more detailed information than was made available in the Delphi study. However, it is interesting to note that despite the limitations of the data, the panels obtained a reasonable degree of consensus and thus appeared to be able to arrive at decisions based on limited information.

In addition to the limitations posed by the composition of the data, the small sample size limited the number of variables that could be assessed in combination with one another. Similarly, the number of different types of patients that could be studied was restricted. Due to these limitations, it must be stressed that the stabilization outcome measure represents but an initial attempt to develop an outcome measure for PHECC. Thus, the stabilization model should be further refined with increases sample size and with additional information included.

Stabilization and Survival

One important aspect of the stabilization outcome measure that has yet to be addressed in the present research is the relationship between stabilization and "final" outcome (in this case, hospital mortality). Although the relationship has yet to be documented, one can reasonably hypothesize that pre-hospital stabilization of patient condition has a positive effect on outcome (if not, the real

effects of EMS intervention are for naught).

To test this hypothesis, the stabilization outcomes for each of the patients in the 93-case data base were predicted using the regression equations derived in Models I and II. These estimates (predictions) of stabilization outcome, referred to as RSTAB1 and RSTAB2, were then compared with patient mortality to determine what type of relationship exists.

To this end, the probabilities of survival for stable and unstable patients were calculated. As shown in Table 33, the probabilities indicate that the stable patient has a greater chance of surviving than does the unstable patient. While not indicative of a strong relationship between stabilization and mortality, it does appear that a positive relationship exists. Furthermore, it should be remembered that the stabilization outcome measure as developed herein considers only pre-hospital stabilization. Ostensibly, consideration of the effects of stabilization in the emergency department and in the coronary care unit would strengthen the relationship.

Application of the Model

The stabilization outcome measure provides a means by which the effects of EMS intervention on patient condition can be directly measured. Accordingly, one possible application of the measure would be as the appropriate response variable (as opposed to survival) for the evaluation design

Table 33. The Relationship Between Stabilization and Survival

Probabilities (P)	Based on the RSTAB1 Prediction	Based on the RSTAB2 Prediction
P(Survival/pt. stable)	.81	.83
P(Survival/pt. unstable)	.70	.70

proposed in conjunction with the index of initial condition, as discussed on page 116.

In addition, the concept of system effectiveness can be defined in terms of stabilization. For example, effectiveness, as measured as a function of an intervention vector, could be defined as a positive change in level of stabilization over time. In this regard, level of stabilization could be assessed at several points in time--notably enroute to the hospital, upon arrival at the emergency department, and upon entry into the coronary care unit.

Summary

In conclusion, the stabilization outcome measure and the index of initial condition are potentially valuable research tools. However, further research is needed to more fully examine the concepts and to explore the possible extensions and applications.

CHAPTER VIII

CONCLUSIONS AND RECOMMENDATIONS

Based upon the research completed in pursuit of the objectives of the thesis, the following conclusions are offered:

1. The index of initial condition (Model B), which was developed in terms of a functional relationship between the dependent variable, hospital mortality, and a number of independent variables (which included vital signs and interactions between vital signs, age, sex, pupil status, level of consciousness, weight, and previous history), is a reasonably valid predictor of short-term survival associated with acute myocardial infarction.

2. High inter-panel agreement was demonstrated with respect to the classification of patients as stable or unstable; moderate inter-panel agreement was demonstrated with respect to classification of patient condition on the nine point stabilization outcome scale.

3. The panels were not as satisfied with the concept of stabilization as would have been desirable. At least some of the dissatisfaction can be attributed to the omission of electrocardiogram readings (due to unavailability of data) level of consciousness, and other patient condition information

(due to the need to minimize the number of independent variables) from consideration in the stabilization experiment.

4. Physician perception of stabilization of the AMI patient is well represented by a multiple linear regression model.

5. Stabilization, as defined herein, appears to be related to short-term survival associated with acute myocardial infarction.

6. Development of a stabilization outcome measure is a reasonable approach by which to represent the clinical outcome of AMI directly attributable to EMS intervention. Due to sample size limitations, the stabilization outcome measure, as developed herein, is but an initial attempt to develop such an intermediate outcome measure.

7. Characteristics of present EMS data systems such as lack of essential information and non-standardization of reporting mechanisms, limit the retrospective development of more sophisticated indices of patient status and other evaluative measures.

It is recognized that the present research represents only an initial attempt to develop an outcome-based evaluation model for PHECC. As such, many refinements are both desirable and necessary. As a result, a number of open research questions exist. Accordingly, the following recommendations suggest possible directions for future research.

1. The index of initial condition and the stabilization

outcome measure should be broadened to include other variables, most notably electrocardiogram readings.

2. Both measures should be validated with prospectively-collected data.

3. The entire experiment should be replicated for a different patient condition. A number of physicians on the panel suggested that the methodology would be more applicable to injuries as opposed to illness. Accordingly, a good candidate for further study would be some type of trauma.

4. Subsequent Delphi experiments should be refined so as to include a panel (or panels) of physicians from places outside the metropolitan Atlanta area. It would then be possible to assess the effects of any local bias in relation to a broader-based group of experts.

5. The use of the index of initial condition as an initial coronary prognostic index should be investigated.

6. Only 20 patient cases were used in the development of the stabilization measure. It is suggested that a larger, statistically-selected sample be used to extend and validate the model.

7. In general, the entire experiment should be expanded to include much larger and more diverse sample sizes.

8. After further examination of the stabilization concept, the relationship between patient stabilization and final outcome (in terms of not only survival but also

disability/morbidity) should be extensively studied.

9. The validated model should be tested in an operational environment. The relationships among stabilization, severity, final outcome, process and input variables should be examined in detail.

10. Present PHECC data collection instruments should be examined with respect to their efficacy for outcome evaluation.[33]

---

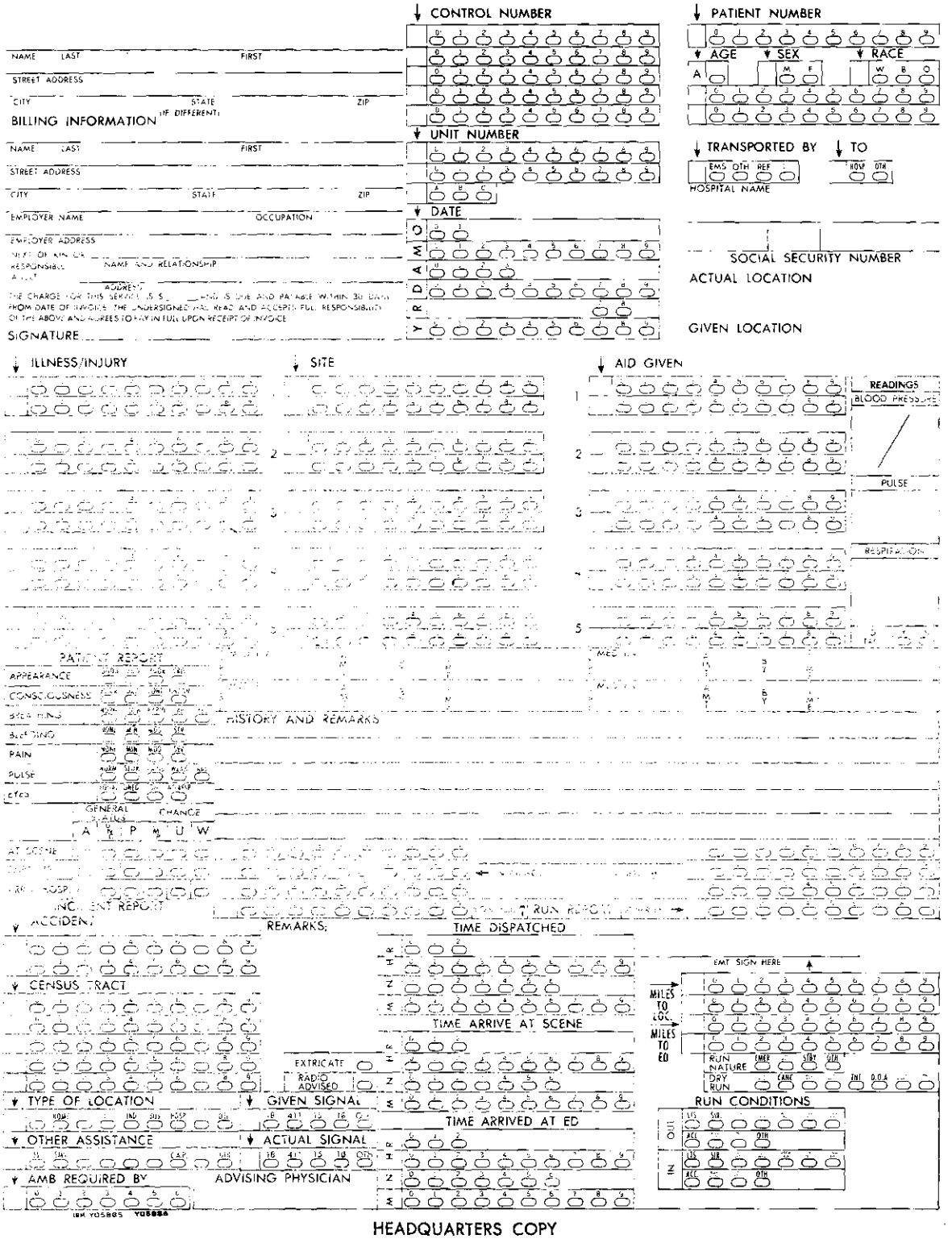
[33]Recently, Polnitsky et al. (1977) have suggested a uniform reporting system for PHECC evaluation. This data set includes much of the information requested by the panels.

APPENDICES

APPENDIX A

AMBULANCE RUN REPORT

This appendix contains a copy of the ambulance run report in use during the study period.



HEADQUARTERS COPY

APPENDIX B

ABSTRACTING FORM

This appendix contains the form developed for the purpose of recording information abstracted from the ambulance run report and the hospital medical record.

AMI ABSTRACTING FORM

Date of Admission_____

Length of Stay_____

Medical Record #_____

Ambulance Run Report #_____

Ambulance Unit #_____

( ) DCFD ( ) GATR

Patient Identification:

Age _____ Sex _____ Race _____ Weight: ( ) Not Obese

( ) Obese

Vital Signs:

	Ambulance	ED	D
SBP	___ ___	___	___
DBP	___ ___	___	___
Pulse	___ ___	___	___
Respiration	___ ___	___	___

Neurological Status (Ambulance):

Pupils	Consciousness	
( ) Equal	( ) Normal	For DCFD
( ) Unequal	( ) Dazed	
( ) Dilated	( ) Confused	
( ) No response	( ) Unconscious	
( ) Equal	( ) Conscious	For GATR
( ) Right larger	( ) Confused	
( ) Left larger	( ) Semi-conscious	
( ) Dilated	( ) Unconscious	
( ) Constricted		
( ) No reaction to light		

Arrhythmias (Ambulance):

( ) None; sinus rhythm
( ) Supraventricular
( ) VPBs; ventricular tachycardia
( ) Ventricular fibrillation
( ) Asystole
( ) Unknown

Severity (Ambulance):

Comments:

( ) Minimal
( ) Moderate
( ) Severe
( ) Critical
( ) DOA
} For DCFD

( ) Minor
( ) Moderate
( ) Critical
( ) Apparent death before arrival
( ) Apparent death after arrival
} For GATR

Change in Condition (Ambulance):

( ) Improved
( ) Unchanged
( ) Worsened
} For DCFD

( ) Improved
( ) Unchanged
( ) Weakened
( ) Apparent death
} For GATR

H-IDCA (8) Final Diagnosis:

( ) 410.0
( ) 410.9
Secondary:_____

History:

( ) Previous MI
( ) Previous angina
( ) Previous CHF
( ) Previous diabetes
( ) Other:_____

Heart Size:

( ) Enlarged
( ) Not enlarged

( ) Confirmed by chest X-ray within 24 hours
( ) Confirmed after 24 hours
( ) No X-ray: _____

Patient Disposition/Follow-up:

( ) DOA
( ) Admitted to hospital
( ) Released from ED
( ) Survived at 24 hrs.
( ) Survived at 48 hrs.
( ) Survived at 72 hrs.
( ) Discharged alive

Response Time:

Dispatch_____

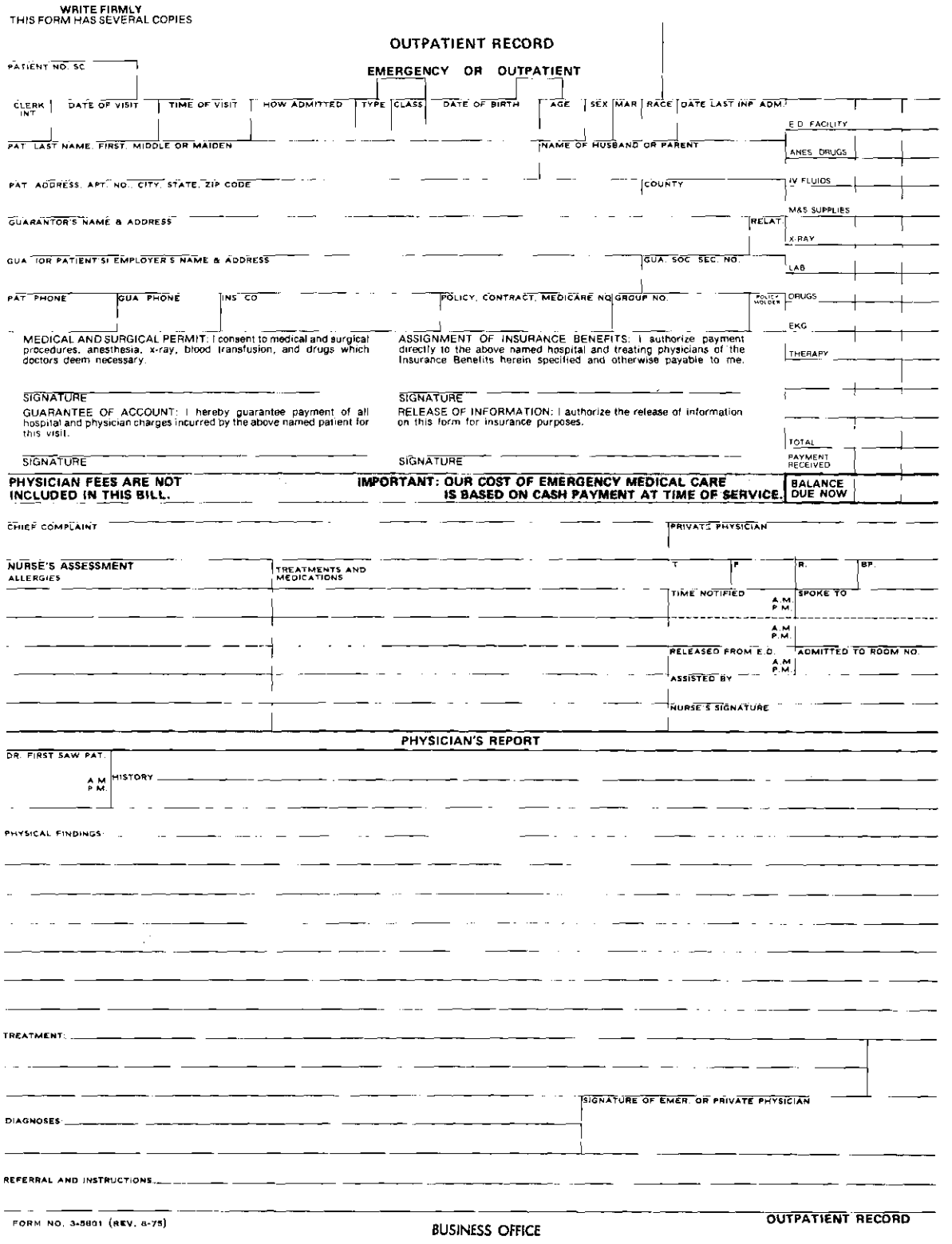
Arrival on scene_____

Arrival at ED_____

APPENDIX C

EMERGENCY DEPARTMENT REPORT

This appendix contains a copy of the emergency department report in use in the test hospital in the study period.



WRITE FIRMLY
THIS FORM HAS SEVERAL COPIES

OUTPATIENT RECORD

EMERGENCY OR OUTPATIENT

PATIENT NO. SC

CLERK INT | DATE OF VISIT | TIME OF VISIT | HOW ADMITTED | TYPE | CLASS | DATE OF BIRTH | AGE | SEX | MAR | RACE | DATE LAST INP. ADM.

PAT. LAST NAME, FIRST, MIDDLE OR MAIDEN | NAME OF HUSBAND OR PARENT

PAT. ADDRESS, APT. NO., CITY, STATE, ZIP CODE | COUNTY

GUARANTOR'S NAME & ADDRESS | RELAT.

GUA. OR PATIENT'S EMPLOYER'S NAME & ADDRESS | GUA. SOC. SEC. NO.

PAT. PHONE | GUA. PHONE | INS. CO | POLICY, CONTRACT, MEDICARE NO. | GROUP NO. | POLICY HOLDER

E.D. FACILITY
ANES. DRUGS
IV FLUIDS
MAS SUPPLIES
X-RAY
LAB
DRUGS
EKG
THERAPY
TOTAL
PAYMENT RECEIVED
BALANCE DUE NOW

MEDICAL AND SURGICAL PERMIT: I consent to medical and surgical procedures, anesthesia, x-ray, blood transfusion, and drugs which doctors deem necessary.

SIGNATURE

GUARANTEE OF ACCOUNT: I hereby guarantee payment of all hospital and physician charges incurred by the above named patient for this visit.

SIGNATURE

ASSIGNMENT OF INSURANCE BENEFITS: I authorize payment directly to the above named hospital and treating physicians of the Insurance Benefits herein specified and otherwise payable to me.

SIGNATURE

RELEASE OF INFORMATION: I authorize the release of information on this form for insurance purposes.

SIGNATURE

PHYSICIAN FEES ARE NOT INCLUDED IN THIS BILL.

IMPORTANT: OUR COST OF EMERGENCY MEDICAL CARE IS BASED ON CASH PAYMENT AT TIME OF SERVICE.

CHIEF COMPLAINT | PRIVATE PHYSICIAN

NURSE'S ASSESSMENT
ALLERGIES | TREATMENTS AND MEDICATIONS | T | P | R. | BP.

TIME NOTIFIED | A.M. P.M. | SPOKE TO

A.M. P.M.

RELEASED FROM E.D. | A.M. P.M. | ADMITTED TO ROOM NO.

ASSISTED BY

NURSE'S SIGNATURE

PHYSICIAN'S REPORT

DR. FIRST SAW PAT. | A.M. P.M. | HISTORY

PHYSICAL FINDINGS

TREATMENT

SIGNATURE OF EMER. OR PRIVATE PHYSICIAN

DIAGNOSES

REFERRAL AND INSTRUCTIONS

FORM NO. 3-5801 (REV. 8-75)

BUSINESS OFFICE

OUTPATIENT RECORD

APPENDIX D

ROUND ONE DELPHI QUESTIONNAIRE

This appendix contains an abbreviated (only two representative patient cases are included) copy of the questionnaire used in the first round of the Delphi study. This questionnaire was distributed to both Panel #1 and #2.

GEORGIA INSTITUTE OF TECHNOLOGY
ATLANTA, GEORGIA 30332

PROGRAM IN HEALTH SYSTEMS
COLLEGE OF ENGINEERING

(404) 894-4550

Thanks so much for agreeing to participate in this expert opinion study. This research study is being conducted as part of my program of study for the Master of Science in Industrial Engineering at Georgia Tech.

As we discussed, the research specifically examines acute myocardial infarctions, and is aimed toward the development of intermediate patient outcome measures for emergency medical services evaluation. These outcome measures will be based upon a patient's clinical status as represented by vital signs. Patient status is viewed in terms of vital signs because it is desired to develop an outcome measure based solely upon commonly available information.

By means of a questionnaire, I would like to obtain your perception of the degree to which a patient's condition is stabilized upon entry into the emergency department as indicated by the change in patient status between the time the patient is first seen by the ambulance attendant and the time that the patient enters the emergency department.

Since you are very busy, I am only asking you to participate because I need your expert input and believe that this study, when completed, can make a contribution to the development of emergency medical services evaluation in this country.

Due to the nature of the study, I can begin computer analysis of the questionnaires only after I have received them all. I would like to pick them up within a week, if at all possible. Thanks for your interest in this study. Please call me at the above number if you have any questions.

Sincerely,

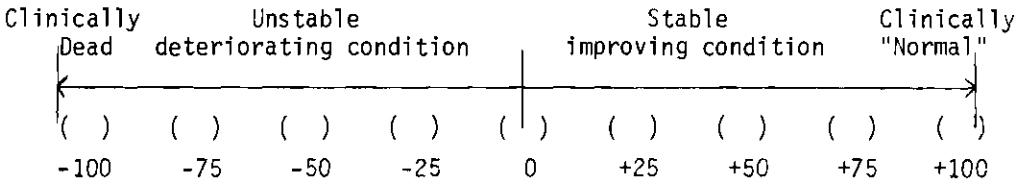
Charles Y. Thomason, III

jh

Enclosures

What do you want me to do?

In this experiment, I am interested in obtaining your perception of the level of "stabilization" of a set of patients based on selected clinical information (e.g., vital signs). "Level of stabilization" will be represented on a stabilization outcome scale, as follows:



As indicated, this scale consists of three primary states: death (-100), stable (0), and normal (+100). Points between these states represent either deteriorating (-25, -50, -75) or improving conditions (+25, +50, +75).

For the purposes of this study, a patient is defined as stable if:

(1) Certain vital signs do not fall below minimum levels.

(2) The patient's condition is not deteriorating at the point of measurement (e.g., upon entry to the emergency department.).

(3) The patient's condition *after emergency procedures have been performed* is improved or unchanged with respect to the patient's condition before treatment. The change in condition is to be measured in terms of vital signs.

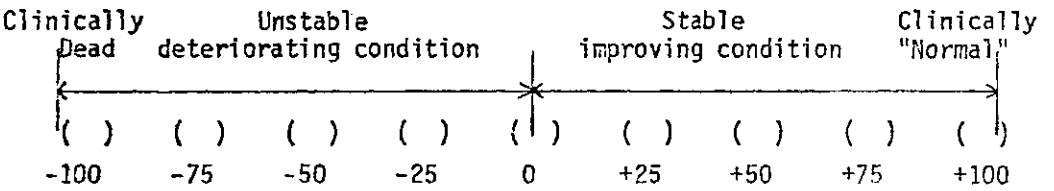
How will my input be obtained?

In order to conserve your valuable time, a structured group opinion method known as the Delphi technique will be used. The Delphi technique employs questionnaires to obtain information from a group of individuals. After the questionnaires are completed, individual responses are combined and a "group response" is compiled. Subsequently, this group response and any pertinent comments from individuals are "fed back" to the individuals together with a second questionnaire. Given the new information, individuals are requested to revise or refine their previous responses. The objective is to obtain agreement among the group of individuals.

Case #: 87 Age: 47 Sex: M Race: W

Vital Signs:	On Scene	In Emergency Department	Change
SBP	160	120	-40
DBP	100	90	-10
Pulse	110	100	+10
Respiration	24	24	0

Level of Stabilization: (Check one block.)

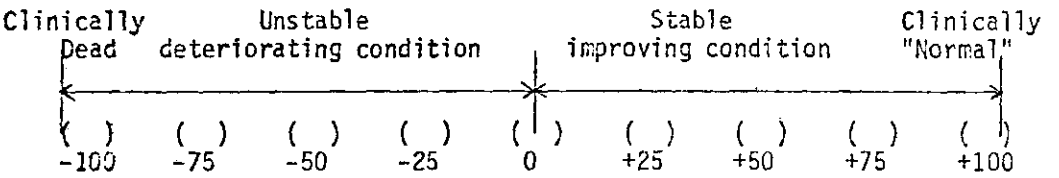


Reasons/Comments:

Case #: 89 Age: 46 Sex: F Race: B

Vital Signs:	On Scene	In Emergency Department	Change
SBP	0	180	+180
DBP	0	100	+100
Pulse	0	80	+80
Respiration	0	20	+20

Level of Stabilization: (Check one block.)



Reasons/Comments:

APPENDIX E

ROUND TWO DELPHI QUESTIONNAIRE--PANEL #1 VERSION

This appendix contains an abbreviated copy of the questionnaire used in the second round of the Delphi study. This version of the questionnaire includes feed-back information generated in round one by Panel #1.

November 10, 1976

Dear Dr.

Thank you for taking time to fill out my questionnaire concerning the pre-hospital emergency stabilization of acute myocardial infarction patients. As you recall, a number of other physicians in the Atlanta area are participating in this study and the objective is to seek agreement among this "panel" of physicians with respect to a quantitative measure of the patient's level of stabilization.

Enclosed is a second questionnaire in which you are requested to reassess your perception of patient condition in light of other responses. To assist you in your reassessment, the average response of the panel, along with pertinent comments, is listed for each patient case.

When you complete this questionnaire, please return it in the enclosed stamped envelope. Since I am rapidly approaching my thesis deadline, I would appreciate it if you would mail the questionnaire within a week, if at all possible. Again, please call me if you have any questions (Day: 894-4556; Evening: 262-7921).

Thank you for participating in this study. Your interest and support are greatly appreciated.

Sincerely,

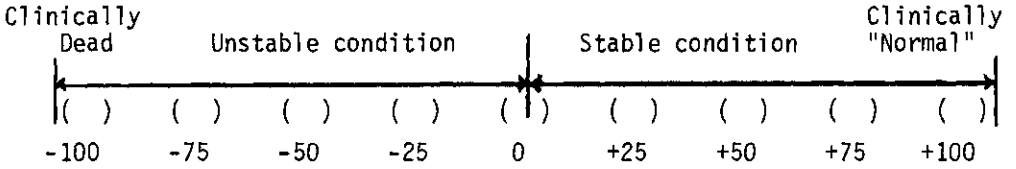
Charles Y. Thomason, III

jc

Enclosures

What do you want me to do?

In this second and final phase of the experiment, I am interested in obtaining your reassessment of the level of "stabilization" of a set of patients based on selected clinical information (e.g., vital signs). "Level of stabilization" will again be represented on a stabilization outcome scale. Please note that the scale has been altered to help improve its interpretation.



As indicated, this scale consists of three primary states: death (-100), stable (0), and normal (+100). Points between these states represent either unstable (-25, -50, -75) or stable conditions (+25, +50, +75).

For the purposes of this study, a patient is defined as STABLE if and only if:

(1) Certain vital signs do not fall below minimum levels.

(2) The patient's condition is not deteriorating at the point of measurement (e.g., upon entry to the emergency department.).

(3) The patient's condition *after emergency procedures have been performed* is improved or unchanged with respect to the patient's condition before treatment. The change in condition is to be measured in terms of vital signs.

A patient is defined as UNSTABLE if any ONE of the above conditions is not satisfied.

Given the definitions of stable and unstable, the various points on the scale are further defined as follows:

+100	Patient stabilized -- condition clinically normal.
+75 +50 +25	Patient stabilized -- all three of the conditions for stabilization are satisfied -- intermediate levels of stabilization -- the higher the rating, the better the prognosis.
0	Patient barely stabilized -- lowest level of condition for a stable patient -- patient questionably stabilized.
-25 -50 -75	Patient unstable -- one or more of the three conditions for stabilization are not satisfied -- the lower the rating, the worse the prognosis.
-100	Patient clinically dead.

INSTRUCTIONS: *For each of the following patients, please indicate your reassessment of the level at which you perceive the patient to be stabilized according to the definition given on the previous page. PLEASE NOTE THAT ALL OF THE PATIENTS HAVE HAD A HOSPITAL DIAGNOSED INFARCTION.*

Case #: 87 Age: 47 Sex: M Race: W

Vital Signs:	On Scene	In Emergency Department	Change
SBP	160	120	−40
DBP	100	90	−10
Pulse	110	100	+10
Respiration	24	24	0

Level of Stabilization: GROUP RESPONSE

Clinically Dead — Unstable condition — Stable condition — Clinically "Normal"

( ) ( ) ( ) ( ) (LO) ( ) ( ) (HI) ( )

-100 -75 -50 -25 0 +25 +50 +75 +100

Representative Comments from the Group:

Low: (No comment).

High: Apprehensive on scene BP.

Other: Minimally significant change--why the rapid respiration?
Slightly improved second degree pulse changes-- may be psychological versus relief of pain

Level of Stabilization: Check one block indicating your REASSESSMENT of the patient's level of stabilization.

Clinically Dead — Unstable condition — Stable condition — Clinically "Normal"

( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( )

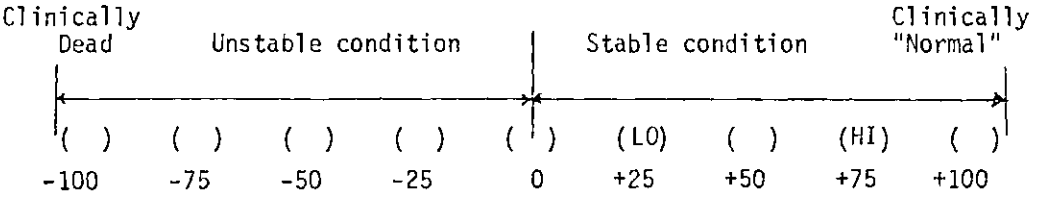
-100 -75 -50 -25 0 +25 +50 +75 +100

INSTRUCTIONS: For each of the following patients, please indicate your reassessment of the level at which you perceive the patient to be stabilized according to the definition given on the previous page. PLEASE NOTE THAT ALL OF THE PATIENTS HAVE HAD A HOSPITAL DIAGNOSED INFARCTION.

Case #: 89 Age: 46 Sex: F Race: B

Vital Signs:	On Scene	In Emergency Department	Change
SBP	0	180	+180
DBP	0	100	+100
Pulse	0	80	+80
Respiration	0	20	+20

Level of Stabilization: GROUP RESPONSE



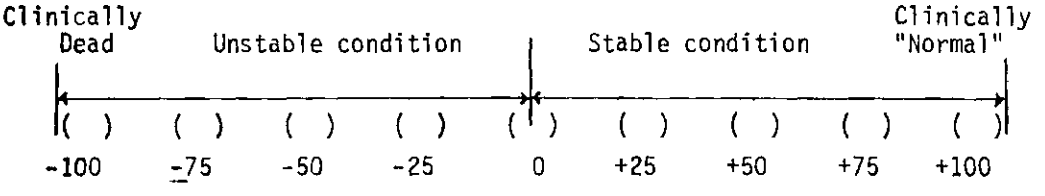
Representative Comments from the Group:

Low: (No comment).

High: Dramatic improvement obviously-- vital signs normal for situation.
Marked improvement but not clinically normal due to increased BP.

Other: (No comment).

Level of Stabilization: Check one block indicating your REASSESSMENT of the patient's level of stabilization.



Supplemental Information

- On the following scale, please indicate the degree of confidence that you have in your estimates of stabilization:

  ( ) Full confidence
  ( ) Much confidence
  ( ) Some confidence
  ( ) Little confidence
  ( ) No confidence

- On the following scale, please indicate your degree of satisfaction with the concept of stabilization (as defined herein) as a basis for developing an intermediate outcome measure for emergency medical services evaluation.

  ( ) Extremely satisfied
  ( ) Very satisfied
  ( ) Adequately satisfied
  ( ) Slightly dissatisfied
  ( ) Extremely dissatisfied.

- In the present study, your perception of level of stabilization was based on limited information. What other information (measured on or before arrival in the ED) would you find helpful in assessing level of stabilization?

- Do you have any additional comments?

- The following biographical information is needed in order to characterize the general make-up of the panel (e.g., the average age of the physicians participating in the study was ___years, ___% were cardiologists, ...).

  Age: ____

  Years in practice: ____

  Specialty: _____

  Sub-specialty: _____

APPENDIX F

ROUND TWO DELPHI QUESTIONNAIRE--PANEL #2 VERSION

This appendix contains an abbreviated copy of the questionnaire used in the second round of the Delphi study. This version of the questionnaire includes feed-back information generated in round one by Panel #2.

November 10, 1976

Dear Dr.

Thank you for taking time to fill out my questionnaire concerning the pre-hospital emergency stabilization of acute myocardial infarction patients. As you recall, a number of other physicians in the Atlanta area are participating in this study and the objective is to seek agreement among this "panel" of physicians with respect to a quantitative measure of the patient's level of stabilization.

Enclosed is a second questionnaire in which you are requested to reassess your perception of patient condition in light of other responses. To assist you in your reassessment, the average response of the panel, along with pertinent comments, is listed for each patient case.

When you complete this questionnaire, please return it in the enclosed stamped envelope. Since I am rapidly approaching my thesis deadline, I would appreciate it if you would mail the questionnaire within a week, if at all possible. Again, please call me if you have any questions (Day: 894-4556; Evening: 262-7921).

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Charles Y. Thomason, III

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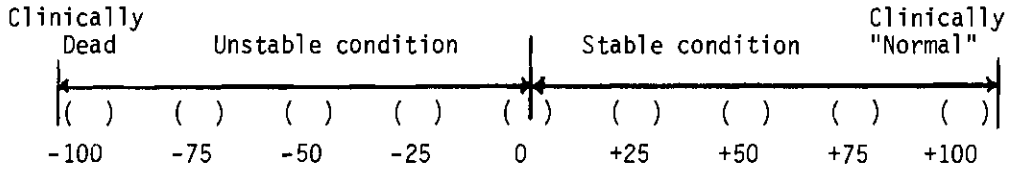
Enclosures

What do you want me to do?

In this second and final phase of the experiment, I am interested in obtaining your reassessment of the level of "stabilization" of a set of patients based on selected clinical information (e.g., vital signs). "Level of stabilization" will again be represented on a stabilization outcome scale. Please note that the scale has been altered to help improve its interpretation.



As indicated, this scale consists of three primary states: death (-100), stable (0), and normal (+100). Points between these states represent either unstable (-25, -50, -75) or stable conditions (+25, +50, +75).

For the purposes of this study, a patient is defined as STABLE if and only if:

(1) Certain vital signs do not fall below minimum levels.

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INSTRUCTIONS: For each of the following patients, please indicate your reassessment of the level at which you perceive the patient to be stabilized according to the definition given on the previous page. PLEASE NOTE THAT ALL OF THE PATIENTS HAVE HAD A HOSPITAL DIAGNOSED INFARCTION.

Case #: 87 Age: 47 Sex: M Race: W

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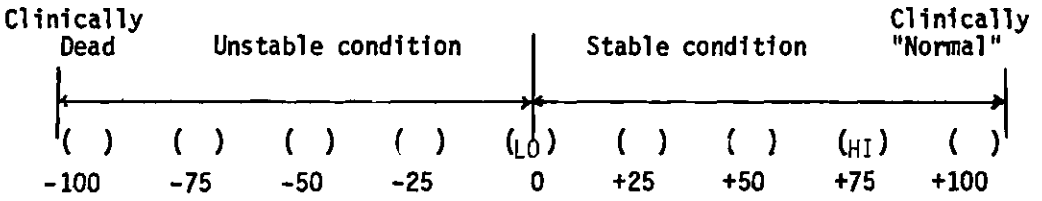
Respiration	24	24	0

Level of Stabilization: GROUP RESPONSE



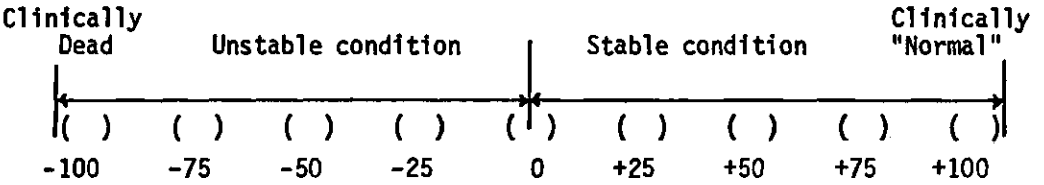
Representative Comments from the Group:

Low: (No comments).

High: Significant improvement.

Other: SBP of 120 may be normal for a man this age.

Level of Stabilization: Check one block indicating your REASSESSMENT of the patient's level of stabilization.



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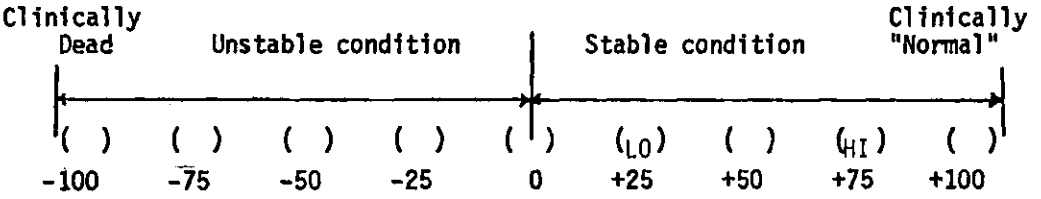
Level of Stabilization: GROUP RESPONSE



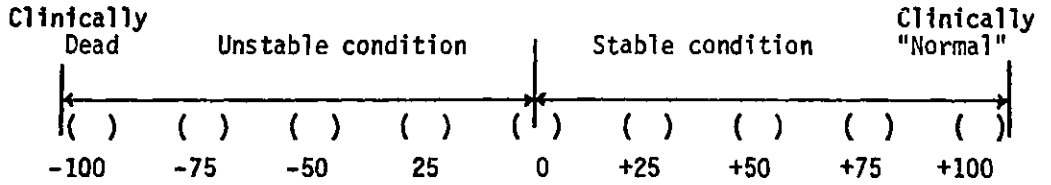
Representative Comments from the Group:

LOW: Good work by EMTs-- still in serious condition and could rapidly deteriorate.

High: Fairly obvious.

Other: (No comments).

Level of Stabilization: Check one block indicating your REASSESSMENT of the patient's level of stabilization.



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- Do you have any additional comments?

- The following biographical information is needed in order to characterize the general make-up of the panel (e.g., the average age of the physicians participating in the study was ___years, ___% were cardiologists, ...).

  Age: ____

  Years in practice: ____

  Specialty: _____

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